

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 March 2002 (21.03.2002)

PCT

(10) International Publication Number
WO 02/22023 A1

(51) International Patent Classification⁷: **A61B 10/00**

(21) International Application Number: PCT/US01/26575

(22) International Filing Date: 24 August 2001 (24.08.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/659,468 11 September 2000 (11.09.2000) US

(71) Applicant: **TYCO HEALTHCARE GROUP LP**
[US/US]; 150 Glover Avenue, Norwalk, CT 06856 (US).

(72) Inventor: **VIOLA, Frank**; 320 Greatquarter Road, Sandy Hook, CT 06482 (US).

(74) Agent: **CRUZ, Lawrence**; Tyco Healthcare Group LP, 150 Glover Avenue, Norwalk, CT 06856 (US).

(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

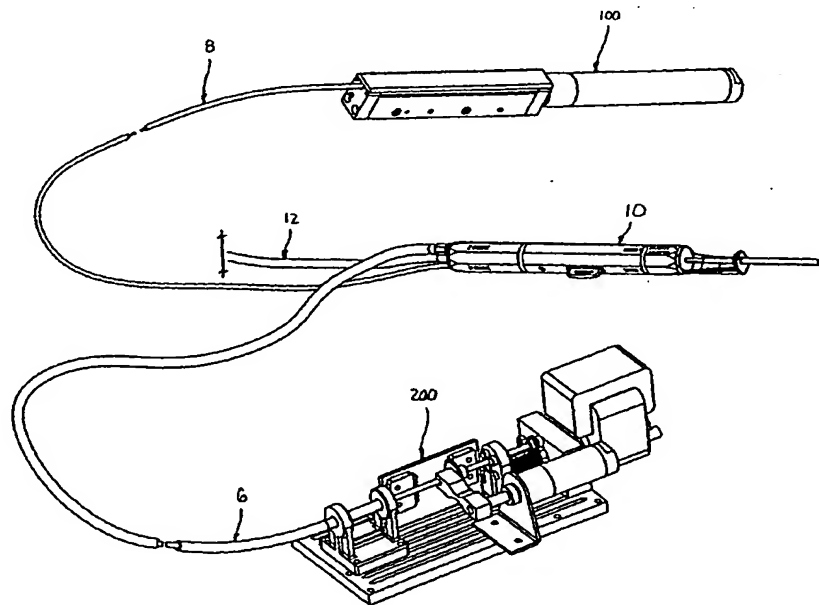
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **BIOPSY SYSTEM**



(57) Abstract: A biopsy system for retrieving biopsy tissue samples from different regions of the body is disclosed. The biopsy system includes a single use loading unit having a trocar assembly and a knife assembly. A trocar driver is operable connected to the trocar assembly and is actuable to move a trocar between retracted and advanced positions. The trocar driver is disengaged from the trocar assembly prior to firing the trocar into a target tissue mass to reduce drag on the trocar during firing. A knife driver is operably connected to the knife assembly such that when actuated, a knife is both rotatably and axially advanced about the trocar.

WO 02/22023 A1

BIOPSY SYSTEM

BACKGROUND

1. Technical Field

This disclosure relates to an apparatus and method for the biopsy of tissue specimens and, more particularly, to a single insertion, multiple sample percutaneous biopsy system and method of use.

2. Background of Related Art

It is often necessary to sample tissue in order to diagnose and treat patients suspected of having cancerous tumors, pre-malignant conditions and other diseases or disorders. Typically, in the case of suspected cancerous tissue, when the physician establishes by means of procedures such as palpation, x-ray or ultrasound imaging that suspicious conditions exist, a biopsy is performed to determine whether the cells are cancerous. Biopsy may be done by an open or percutaneous technique. Open biopsy removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy on the other hand is usually done with a trocar-like instrument and may be either a fine trocar aspiration (FNA) or a core biopsy. In FNA biopsy, individual cells or clusters of cells are obtained for cytologic examination and may be prepared such as in a Papanicolaou smear. In core biopsy, as the term suggests, a core or fragment tissue is obtained for histologic examination which may be done via frozen section or paraffin section. In more recent developments percutaneous techniques have been used to remove the entire mass during the initial procedure.

The type of biopsy utilized depends in large part on the circumstances present with respect

to the patient and no single procedure is ideal for all cases. Core biopsy, however, is extremely useful in a number of conditions and is being used more frequently.

Intact tissue from the organ or lesion is preferred by medical personnel in order to arrive at a definitive diagnosis regarding the patient's condition. In most cases only part of the organ or lesion need be sampled. The portions of tissue extracted must be indicative of the organ or lesion as a whole. In the past, to obtain adequate tissue from organs or lesions within the body, surgery was performed so as to reliably locate, identify and remove the tissue. With present technology, medical imaging equipment such as stereotactic x-ray, fluoroscopy, computer tomography, ultrasound, nuclear medicine and magnetic resonance imaging, may be used. These technologies make it possible to identify small abnormalities even deep within the body. However, definitive tissue characterization still requires obtaining adequate tissue samples to characterize the histology of the organ or lesion.

Mammography can identify non-palpable (not perceptible by touch) breast abnormalities earlier than they can be diagnosed by physical examination. Most non-palpable breast abnormalities are benign but some are malignant. When breast cancer is diagnosed before it becomes palpable, breast cancer mortality can be reduced. It is still difficult to determine if pre-palpable breast abnormalities are malignant, as some benign lesions have mammographic features which mimic malignant lesions and some malignant lesions have mammographic features which mimic benign lesions. Thus, mammography has its limitations. To reach a definitive diagnosis, tissue from within the breast must be removed and examined under a microscope.

The introduction of stereotactic guided percutaneous breast biopsies offered alternatives to open surgical breast biopsy. With time, these guidance systems have become more accurate and easier to use. Biopsy guns were introduced for use in conjunction with these guidance systems.

Accurate placement of the biopsy guns was important to obtain useful biopsy information because only one small core could be obtained per insertion at any one location. To sample the lesion thoroughly, many separate insertions of the instrument had to be made.

Biopsy procedures may benefit from larger tissue samples being taken, for example, tissue samples as large as 10 mm across. Many of the prior art devices required multiple punctures into the breast or organ in order to obtain the necessary samples. This practice is both tedious and time consuming.

One further solution to obtain a larger tissue sample is to utilize a device capable of taking multiple tissue samples with a single insertion of an instrument. An example of such a device is found in U.S. Patent No. 5,195,533 to Chin et al. which describes a technique for extracting multiple samples with a single insertion of the biopsy device. Generally, such biopsy instruments extract a sample of tissue from a tissue mass by either drawing a tissue sample into a hollow trocar via an external vacuum source or by severing and containing a tissue sample within a notch formed on a stylet. Typical of such devices utilizing an external vacuum source are U.S. Patent No. 5,246,011 issued to Cailouette and U.S. Patent No. 5,183,052 issued to Terwiliger. Such devices generally contemplate advancing a hollow trocar into a tissue mass and applying a vacuum force to draw a sample into the trocar and hold the same therein while the tissue is extracted.

When extracting multiple samples with a single insertion of the biopsy device using suction to either draw in tissue or remove the tissue from the body, it is important that the vacuum path remain unclogged. If the vacuum path clogs, the sample removal will become difficult or impossible. This may necessitate multiple insertions of the device or reduce the sample mass per extraction.

Therefore, a continuing need exists for percutaneous biopsy apparatus and methods which can reliably extract adequate biopsy sample(s) with a single insertion of the biopsy instrument.

SUMMARY

In accordance with the present disclosure, a biopsy system is provided which includes a single use loading unit (SULU), a knife driver and a trocar driver. The SULU includes a trocar assembly having a tubular trocar defining a tissue receiving basket, a trocar tip having a basket insert fastened to the trocar, a trocar flange secured to the proximal end of the trocar, and an engagement mechanism for connecting the trocar driver to the trocar. The engagement mechanism includes a connecting member in the form of a notched flag. The connecting member is secured to one end of a drive shaft which extends between the trocar driver and the SULU. The notched flag is positioned to engage the trocar flange such that axial movement of the drive shaft effected by the trocar driver is translated to axial movement of the trocar. The connecting member is pivotable out of engagement with the trocar flange to disengage the trocar driver from the trocar to reduce drag on the system during firing of the trocar and enable advancement of the trocar into a target tissue mass at a higher velocity.

The knife assembly includes a tubular knife which is slidably positioned about the trocar. The knife has a sharpened distal edge and defines a tissue access window adjacent its proximal end. The knife is connected to knife driver through a flexible drive shaft and gear assembly such that the knife is both rotatably and axially driven by the knife driver.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present disclosure are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of one embodiment of a biopsy system constructed in

accordance with the principles of the present disclosure;

FIG. 2 is a perspective view of the single use loading unit ("SULU") of the biopsy system shown in FIG. 1;

FIG. 3 is a perspective view with parts separated of the SULU shown in FIG. 2;

FIG. 3A is a perspective view of the internal gear of the SULU shown in FIG. 3;

FIG. 4 is a side cross-sectional view of the SULU shown in FIG. 2;

FIG. 5 is a side cross-sectional view of the forward end of the SULU shown in FIG. 2;

FIG. 6 is a side cross-sectional view of the distal end of the SULU shown in FIG. 2;

FIG. 7 is a perspective view of a portion of the knife assembly of the SULU shown in FIG. 2;

FIG. 8 is a perspective view with parts separated of the portion of the knife assembly shown in FIG. 7;

FIG. 9 is a perspective view with parts separated of the proximal end of the push/pull cable of the biopsy system shown in FIG. 1;

FIG. 10 is a perspective view of the proximal end of the push/pull cable of the biopsy system shown in FIG. 9;

FIG. 11 is a perspective view of the central portion of the SULU shown in FIG. 2 with the tubular body removed;

FIG. 12 is a perspective, partial cutaway view of the central portion of the SULU shown in FIG. 2 with the tubular body removed;

FIG. 13 is a perspective view of the knife driver of the biopsy system shown in FIG. 1;

FIG. 14 is a perspective view with parts separated of the knife driver shown in FIG. 13;

FIG. 15 is a perspective view of the trocar driver of the biopsy system shown in FIG. 1;

FIG. 16 is a perspective view with parts separated of the trocar driver shown in FIG. 15;

FIG. 17 is a side cross-sectional view of the trocar driver shown in FIG. 15;

FIG. 18 is a cross-sectional view taken along section lines 18-18 of FIG. 17;

FIG. 19 is a perspective view of the firing module for use with the SULU shown in FIG.

2;

FIG. 20 is a perspective view of the SULU shown in FIG. 2 with the firing module shown in FIG. 19 attached thereto;

FIG. 21 is a perspective view of the SULU as shown in FIG. 2 positioned adjacent to a mounting cradle;

FIG. 22 is a perspective view of the SULU shown in FIG. 2 supported on the mounting cradle;

FIG. 23 is a perspective view of the SULU/cradle assembly shown in FIG. 22 positioned adjacent a table mount;

FIG. 24 is a perspective view of the SULU/cradle assembly shown in FIG. 24 positioned on a table mount;

FIG. 25 is a side view illustrating the relative alignment of the SULU with a target tissue in a clamped breast prior to insertion of the trocar tip;

FIG. 26 is a side cross-sectional view of the trocar driver shown in FIG. 15 in the advanced position;

FIG. 27 is an enlarged view of the indicated area of detail of FIG. 13;

FIG. 28 is a cross-sectional view taken along section lines 28-28 in FIG. 17;

FIG. 29 is a side view of the tri-roller bearing assembly and shaft of the knife driver of FIG. 13;

FIG. 30 is a side partial cross-sectional view of the central portion of the SULU with the knife assembly in the retracted position;

FIG. 31 is a side partial cross-sectional view of the central portion of the SULU with the knife assembly in a partially advanced position;

FIG. 32 is a side cross-sectional view of the distal end of the SULU disposed within a target tissue mass with the trocar assembly in the advanced position and the knife assembly in the retracted position and a vacuum drawing tissue into the basket;

FIG. 33 is a side cross-sectional view of the distal end of the SULU disposed within a target tissue mass with the trocar assembly and the knife assembly in the advanced positions and a severed tissue sample in the basket;

FIG. 34 is a side cross-sectional view of a central portion of the SULU with the trocar in the retracted position and the basket disposed adjacent the tissue access window, wherein a tissue sample is being removed from the window.

FIG. 35 is a side cross-sectional view of the distal end of the SULU disposed within a target tissue mass with the knife assembly and the trocar assembly in the advanced position;

FIG. 36 is a side cross-sectional view of the forward end of the SULU disposed within a target tissue mass with the trocar assembly in a retracted position and a tissue marking device extending through the tubular knife;

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the presently disclosed biopsy system will now be described in detail with reference to the drawings, wherein like reference numerals designate corresponding elements in each of the several views.

The following U.S. Patents and/or applications disclose related subject matter and are

incorporated herein, in their entirety, by reference: U.S. Patent No. 5,782,775, filed January 14, 1996; U.S. Patent No. 6,050,955, filed September 18, 1998; U.S. Patent No. 6,019,733, filed September 18, 1998; U.S. Patent No. 6,007,495, filed January 22, 1998; U.S. patent application Serial No. 09/252,548, filed February 19, 1999 and U.S. patent application Serial No. 09/448,238, filed November 24, 1999.

The presently disclosed biopsy system is illustrated in FIG. 1 and includes a single use loading unit (SULU) 10, a trocar driver 100 and a knife driver 200. A knife driver cable 6 extends between knife driver 200 and SULU 10, and a push/pull cable 8 extends between trocar driver 100 and SULU 10. Trocar driver 100 and knife driver 200 will be described in further detail hereinbelow. A vacuum line 12 adapted to be connected to a vacuum source (not shown) is connected to SULU 10.

Referring to FIGS. 2 and 3, SULU 10 includes a trocar assembly and a knife assembly. The trocar assembly and the knife assembly are housed within tubular body 14 which defines a cylindrical throughbore 16. Tubular body 14 is preferably formed of aluminum but may be formed of any material having the requisite strength requirements including for example plastics. The outer surface of tubular body 14 is preferably hexagonal and defines a series of flats 18. Some or all of the flats may include indicia 20 to indicate the orientation of SULU 10. Two sets of indicia may be provided on each flat 18 to facilitate operation of SULU 10 from either side of the instrument. Alternately, the outer surface of SULU 10 can have a variety of configurations, e.g., cylindrical, pentagonal, square, etc.

Referring to FIGS. 3-6, the trocar assembly includes a tubular trocar 22 having a distal end 24 and a proximal end 26. Distal end 24 of trocar 22 includes a cutout which defines a tissue receiving basket 28. A trocar tip 30 having a perforated basket insert 32 is fastened to distal end

24 of trocar 22 such that basket insert 32 is positioned within tissue receiving basket 28 of trocar 22. Trocar tip 30 can be fastened within distal end of trocar 22 using any known fastening technique including crimping, adhesives, laser welding, etc.

Proximal end 26 of trocar 22 is fastened to a trocar flange 34 using any known fastening technique including, crimping, welding, adhesives, etc. Trocar flange 34 includes a pair of notches 36 and 38. Notch 36 is semi-spherically shaped and is dimensioned to slidably engage the outer surface of tubular member 40 see FIGS. 11 and 12. Tubular member 40 acts as a guide to maintain alignment of trocar flange 34 as it is moved through tubular body 14 by trocar driver 100 (FIG. 1). Tubular member 40 also forms part of the knife assembly and will be described in further detail below. Notch 38 of trocar flange 34 is configured to receive a flag 42. Flag 42 is preferably formed from a piece of folded sheet metal which is fastened to a first end of push/pull core 43 of push/pull cable 8. Alternately, flag 42 may be formed from other materials having the requisite strength requirements including plastic, etc. The second end of push/pull core 43 is secured within trocar driver 100 and will be described in further detail below. Flag 42 is preferably crimped to push/pull core 43 but other known fastening techniques may be used.

Referring also to FIG. 12, flag 42 is slidably positioned within a C-tube 46 which includes a central bore 48 and a radial slot 50. Hub 52 of flag 42 is fastened about push/pull core 43 and is slidably positioned within central bore 48 of C-tube 46. Central bore 48 of C-tube 46 is dimensioned to prevent buckling of push/pull core 43. Pennant portion 54 of flag 42 extends through radial slot 50 and includes a notch 56 which is positionable to engage trocar flange 34 adjacent notch 38. When flag 42 is positioned to engage trocar flange 34, any axial movement of driver shaft 43 is translated to axial movement of trocar flange 34, trocar 22 and trocar tip 30. C-tube 46 is rotatable to pivot pennant portion 54 and moves notch 56 from engagement with trocar

flange 34 to disengage flag 42 from trocar flange 34. A spring 55 connected between a retainer 76 and C-tube 46 urges C-tube 46 to a position in which notch 56 is engaged with trocar flange 34. This will be discussed in further detail below.

Referring to FIGS. 3-8, the knife assembly includes a tubular knife 58 which is slidably positioned about trocar 22 and has an annular sharpened edge 60 formed at its distal end 62. A cutout formed towards proximal end 66 of knife 58 defines a tissue access window 64. A knife gear 68 is fastened to proximal end 66 of knife 58. Knife gear 68 is preferably molded about proximal end 66 of knife 58. Alternately, gear 68 can be fastened to proximal end 66 using any known fastening technique including welding, adhesives, crimping, etc. An internal gear 70 is positioned in a forward chamber 72 defined in tubular body 14 between a nosepiece 74 and a retainer 76. See FIG. 11. Nosepiece 74 and retainer 76 are fastened within throughbore 16 of tubular body 14 using any known fastening technique including welding, adhesives, etc. Knife gear 68 includes teeth 78 which engage teeth 80 formed on internal gear 70. A spring 82 is positioned about knife 58 between knife gear 68 and nosepiece 74. Spring 82 is positioned to urge knife gear 68 towards retainer 76 to urge knife 58 to a retracted position. Knife gear 68 includes a central throughbore 77 which is dimensioned to receive vacuum tube 95.

Tubular member 40 is positioned within a rear chamber 84 defined within tubular body 14 of SULU 10 between retainer 76 and an end cap 86. A pin 85 projects outwardly from tubular member 40. Pin 85 is received within an internal slot formed in end cap 86 to form a bayonet-type coupling therewith. See FIG. 11. A connector 88 is provided on a proximal end 90 of tubular member 40 to facilitate connecting tubular member 40 to an outer sheath 225 (FIG. 13) of knife driver cable 6. A bearing member 88' is secured to the distal of tubular member 40. A solid straight shaft 92 extends through tubular member 40 and includes a reduced diameter end portion

94 which extends through an opening in bearing member 88'. One end of shaft 92 is fastened to inner flexible shaft 226 of knife driver cable 6 (FIG. 13). A drive gear 96 is fastened to reduced diameter end portion 94 of shaft 92. Drive gear 96 can be fastened to shaft 92 using any known fastening technique including welding, crimping, brazing, etc. Drive gear 96 includes gear teeth 96'. A spherical nose 98 of end portion 94 extends axially from drive gear 96. Gear teeth 96' mesh with internal gear teeth 80 of internal gear 70 such that upon rotation of drive gear 96 by knife driver 200, internal gear 70 is rotated. Rotation of internal gear 70 causes knife gear 68 to rotate to provide corresponding rotation of knife 58. Spherical nose 98 of reduced diameter end portion 94 is positioned to engage the rear end of knife gear 68 such that when inner flexible shaft 226 of knife driver cable 6 is advanced by knife driver 200, spherical nose 98 of shaft 92 urges knife gear 68 axially along a path defined by internal gear teeth 80 to advance knife 58 axially. See FIG. 31. When drive gear 96 is retracted by knife driver 200, spring 82 returns knife gear 68 to its retracted position adjacent retainer 76.

Referring again to FIG. 3, a vacuum tube 95 extends into trocar 22. Vacuum tube 95 may include an outer seal (not shown) to seal between the internal surface of trocar 22 and the outer surface of vacuum tube 95. The proximal end of vacuum tube 95 is connected to an offset fitting 93 which is received in a bore 99 formed in end cap 86. Offset fitting 93 includes a plug 97 adapted to be sealingly received within one end of a vacuum line 12. Vacuum tube 95 is positioned to facilitate creation of a vacuum within trocar 22 to draw tissue into tissue receiving basket 28 of trocar 22.

A slide 2 including a pair of flexible legs 3 is adjustably mounted to nosepiece 74. Each leg 3 is resilient and includes a detent which is positionable in one of multiple grooves (not shown) formed in nosepiece 74. A bore 4 is formed in a base portion 5 of slide 2. Bore 4 is

dimensioned to receive a tube 7 formed of a radiotranslucent material. Tube 7 is positioned about the distal end of knife 58 and trocar 22. Slide 2 is adjustable with respect to nosepiece 74 to selectively cover a portion of basket 28. Such is necessary when the length of basket 28 exceeds the width of the target tissue mass.

Referring to FIGS. 11 and 12, as discussed above, a retainer 76 and an end cap 86 define a rear chamber 84 within tubular body 14. Retainer 76 and end cap 86 include openings which define bearing surfaces for supporting C-tube 46, vacuum tube 95 and tubular member 40. A shipping tab 79 extends through opening 81 (FIG. 3) in tubular body 14 into rear chamber 84 and engages trocar flange 34 to prevent axial movement of trocar 22 during shipping and/or during attachment of SULU 10 to trocar driver 100.

Preferably, SULU 10, excluding tubular member 40, solid shaft 94 and drive gear 96, is disposable after use. Cable 8 including push/pull core 43 may also be disposable. Tubular member 40, shaft 92 and drive gear 96 can be removed from SULU 10 by rotating connector 88 and tubular member 40 approximately 90° to disengage bayonet pin 85 from end cap 86 and, thereafter, pulling tubular member 40 and drive gear 96 through the opening 76' (FIG. 11) formed in retainer 76. Preferably, the disposable components of SULU 10 are constructed from engineering grade plastics, e.g., polycarbonates, nylon, delrin or like materials. The non-disposable elements, e.g., drive gear 96, may be formed of metal, e.g., stainless steel or other reusable materials having the requisite strength requirements.

Referring to FIGS. 15-18, trocar driver 100 includes a housing 110 formed of a pair of symmetrical housing halves 110a and 110b which define a cylindrical throughbore 112, a spherically shaped recess 115 (FIG. 18) and a radially extending slot 114 extending between throughbore 112 and cylindrical recess 115. Housing halves 110a and 110b are preferably

secured together with screws 116, although other fastening techniques may be used to secure the housing halves together. A pivotable lid 118 is pivotably secured about rod 120 (FIG. 18) to housing halve 110a. Lid 118 is pivotable to permit access to slot 114 during loading of push/pull core 43 into needle driver 100.

A first mounting block 120 is secured to one end of housing 110 using screws 122 or other known fastening techniques. Mounting block 120 includes a threaded throughbore 124 configured to threadably receive a threaded end 125 of drive cylinder 126. Drive cylinder 126 includes a drive member 128 which is configured to be slidably positioned within cylindrical throughbore 112. Drive member 128 includes an annular recess 130. A second mounting block 132 is secured to the end of housing 110 opposite mounting block 120 using screws 134. Second mounting block 132 includes a U-shaped slot 136. Lid 118 includes an extension 138 which covers U-shaped slot 136 when lid 118 is in a closed position. U-shaped slot 136 is dimensioned to allow passage of push/pull cable 8 and includes a pair of flat sidewalls 140. Second mounting block 132 also includes a threaded bore 142 dimensioned to receive a threaded stop 144. Threaded stop 144 can be selectively positioned within throughbore 112 to set the maximum stroke of drive member 128.

Push/pull cable 8 includes an outer sheath 146 and push/pull core 43. A rectangular fitting 147 is secured to one end of outer sheath 146. Fitting 147 is positioned between sidewalls 140 of mounting block 132 to fix outer sheath 146 relative to mounting block 132. Push/pull core 43 is slidably positioned within outer sheath 146. A second flag 148 is fastened to the end of push/pull core 43 opposite flag 42. As discussed above with respect to flag 42, flag 148 is formed from a piece of folded sheet metal which is crimped or fastened in some other manner to push/pull core 43. Second flag 148 includes a hub portion 150 and a pennant portion 152 having

a tongue 154 which is dimensioned to be received within annular recess 130 of drive member 128.

Prior to operating the biopsy system, flag 148 and push/pull core 43 are secured within trocar driver 100 by positioning push/pull core 43 and hub portion 150 in recess 115 with pennant portion 152 of flag 148 extending through radially extending slot 114 and tongue 154 extending into annular recess 130 of drive member 128. Recess 115 is dimensioned to prevent buckling of push/pull core 43. To facilitate installation of flag 148 into trocar driver 100, each end of housing halves 110a and 110b include a stepped portion 156 adjacent each end of radially extending slot 114. Stepped portions 156 are in juxtaposed alignment when housing halves 110a and 110b are fastened together to provide an enlarged slot 158 to accommodate installation of hub portion 150 of flag 148 into recess 115.

Referring to FIGS. 13, 14 and 27-29, knife driver 200 includes a motor 210, a drive gear 212, a driven gear 214, a tri-roller bearing assembly 216, a return actuator 218, a forward bearing assembly 220, a limit switch assembly 222, and a baseplate 223. Motor 210 is preferably a DC servo motor or an AC motor. In the alternative, motor 210 can be any type of electrically, hydraulically or pneumatically driven motor. Motor 210 turns drive gear 212 which in turn drives driven gear 214. Driven gear 214 is connected to a cylindrical shaft 224 using a known fastening technique, e.g., crimping, welding, etc., such that upon rotation of driven gear 214, shaft 224 is rotatably driven. Shaft 224 is preferably a solid metal shaft, but may be hollow and formed of any material having the requisite strength requirements. Shaft 224 extends from driven gear 214 and extends through tri-roller bearing assembly 216 into outer sheath 225 of knife driver cable 6. Knife driver cable 6 includes outer sheath 225 and inner flexible shaft 226. Inner flexible shaft 226 preferably includes a solid core diameter with alternately wound layers about the solid core

diameter. Alternately, different types of flexible shafts capable of accurately translating rotational and axial movement to the knife assembly of SULU 10 may be used. Shaft 224 is secured to flexible shaft 226 such as by welding, although other fastening techniques may be employed.

Referring specifically to FIGS. 27 and 28, tri-roller bearing assembly 216 includes three bearing elements 230 mounted on bearing support 232. Each of bearing elements 230 is oriented and configured to have contact surfaces 234 which form a partially helical thread configuration and effects axial translation of shaft 224 as shaft 224 is rotated by driven gear 214. Specifically, each of bearing elements 230 is tilted at an angle α which is offset from the longitudinal axis (FIG. 29). This angle of offset α may be chosen to achieve a desired rate of advancement per revolution of shaft 224. One effective angle for present purposes is approximately 2° , although other offset angles are envisioned.

Return actuator 218 includes a cylinder 238 and a piston 240. A follower 242 is connected to piston 240. Follower 242 includes a U-shaped recess 244 dimensioned to be positioned about shaft 224. A disc 246 is fixedly secured to shaft 224 and is positioned behind follower 242. As shaft 224 is rotated and advanced axially, follower 224 is pushed axially to extend piston 240 from within cylinder 238. When it is desired to return shaft 224 to its retracted position, a vacuum is effected within cylinder 238 to retract piston 240. When piston 240 is retracted, follower 242 urges disc 246 rearwardly to return shaft 224 to its retracted position. The return force applied to shaft 224 by return actuator 218 must be greater than the slip force applied on shaft 224 by tri-roller bearing assembly 216. Currently, the slip force applied on shaft 224 by tri-roller assembly 216 is approximately 2 lbs. and the return force applied by return actuator 218 is approximately 9 lbs.

A side bracket 250 is secured to baseplate 223. Limit switch assembly 222 is supported on side bracket 250 and includes a pair of limit switches 252 and 254. Limit switch 252 is positioned to engage disc 246 to release the vacuum from air cylinder 238 after piston 240 and shaft 224 have been moved to their retracted position. Limit switch 254 is positioned to engage disc 246 to shut down motor 210 when shaft 224 has reached the predetermined end of its stroke.

Typically, bearing elements 230 are spaced 120° apart. Alternately, as illustrated in FIG. 28, the spacing between the two uppermost bearing elements may be increased to allow shaft 224 to be snap fit in between the uppermost bearing elements 230. The lowermost bearing element is spring mounted on a slide 235 which is slidably positioned within an elongated vertical recess 232' formed in bearing support 232. A pair of screws 237 retain slide 235 slidably positioned within recess 232'. A spring (not shown) positioned in the bottom of slide 235, urges slide 235 and bearing 230 upwardly. By mounting one of the bearing elements 230 on a spring mounted slide, the tolerances normally required to achieve the desired slip force are no longer necessary and the desired slip force can be more easily attained.

Referring to FIGS. 19 and 20, a firing module 300 is adapted to engage tubular body 14 of SULLU 10 to effect firing of trocar 22 into tissue. Firing module 300 includes a support member 302, a firing lever 304, and a positioning bracket 306. Support member 302 defines a concavity 303 configured to receive SULLU 10. Positioning bracket 306 includes a plurality of fingers 308 which engage and retain SULLU 10 on support member 302 in concavity 303 when SULLU 10 is supported thereon.

Firing module 300 includes a handle assembly including a movable handle 310 and a stationary handle 312. Movable handle 310 can be compressed towards stationary handle 312 to load firing lever 304. When movable handle 310 is moved towards stationary handle 312,

support member 302 is moved away from positioning bracket 306 to allow SULU 10 to be positioned in concavity 303 of support member 302. When movable handle 310 is released, support member 302 moves in the direction indicated by arrow "A" to clamp SULU 10 between support member 302 and positioning bracket 306 such as shown in FIG. 20.

Referring also to FIG. 21, tubular body 14 of SULU 10 includes an elongated slot 316. When firing module 300 is attached to SULU 10, firing lever 304 extends through slot 316 to a position behind trocar flange 34 (see FIG. 4). A release pin 318 is positioned on support member 302. Release pin 320 is positioned to extend through opening 322 formed in tubular body 14 (FIG. 2) and engage a pin 324 formed on C-tube 46. Engagement between release pin 320 and pin 324 causes C-tube 46 to rotate slightly, moving notch 56 out of engagement with trocar flange 34. By disengaging flag 42 from trocar flange prior to firing, the drag on the firing module is greatly reduced, allowing trocar 22 and trocar tip 30 to be accelerated more quickly and thus, advanced at a greater velocity into a targeted tissue mass.

Referring to FIGS. 21 and 22, SULU 10 can be hand held during operation, or in the alternative, SULU 10 can be supported on the instrument stage of a stereotactic imaging table. When SULU 10 is supported on an instrument stage, SULU 10 is first supported on a cradle 400. Cradle 400 includes a pair of spaced resilient arms 402 and 403 positioned at each end of a base member 404. Each pair of spaced arms defines a concavity 406 for receiving one end of SULU 10. Tubular body 14 of SULU 10 includes a pair of annular grooves 408 and 409. Arms 402 and 403 are dimensioned to be received within grooves 408 and 409 to axially fix SULU 10 in relation to cradle 400.

Referring to FIGS. 23 and 24, when SULU 10 is used in conjunction with an imaging table, cradle 400 is secured to stage or table mount 420. Typically, table mount 420 includes a

plurality of protrusions 422 which are dimensioned to be received in holes 424 formed in cradle 400. Protrusions 422 on table mount 420 and holes 424 in cradle 400 are located to properly position SULU 10 on the imaging table.

Referring to FIGS. 25, 26 and 30-35, the operation of the biopsy system will now be described for use in connection with a biopsy procedure performed on a breast of a patient. It is to be understood, however, that the procedures described herein may also be utilized in connection with the biopsy of tissue in other regions of the body.

As discussed above, SULU 10 can be hand-held during use or supported on an imaging table. The following description is directed to use of the biopsy system after it has been positioned on an imaging table.

First, cradle 400 is secured to table mount 420. Next, shipping tab 79 is removed from slot 316 of SULU 10 and firing module 300 is clamped to SULU 10 in the manner discussed above such that firing lever 304 extends through opening 316 of tubular body 14 and engages the rear end of trocar flange 34. Attachment of firing module 300 to SULU 10 also effects rotation of C-tube 46 to disengage notch 56 of flag 42 from trocar flange 34. As discussed above, by disengaging flag 42 from trocar flange 34, drag on the firing module 300 is reduced and trocar 22 can be accelerated more quickly to a higher velocity prior to engaging the targeted tissue mass 450.

After SULU 10 has been secured within cradle 400 on table mount 420, SULU 10 is moved using table mount 420 in association with a stereotactic imaging apparatus to a position in which trocar tip 30 is aligned with the center of a targeted tissue mass 450. With trocar 22 and tubular knife 58 in a retracted position, trocar tip 30 is targeted, i.e., advanced to a position approximately 17 mm in front of targeted tissue mass 450. See FIG. 25.

Next, a release button (not shown) on firing module 300 is actuated to release firing lever 304 to advance trocar flange 34 and trocar 22 into targeted tissue mass 450. See FIG. 32. In this position trocar 22 is in the advanced position with receiving basket 28 positioned within targeted tissue mass 450, and knife 58 is in the retracted position.

At this point, a vacuum is drawn through vacuum tube 95, trocar 22 and basket insert 32 via vacuum line 12 (FIG. 3) to draw tissue into basket 28. After tissue has been drawn into basket 28, knife driver can be actuated to advance knife 58 over trocar 22 (FIG. 33). As discussed above, knife driver 200 advances and rotates knife 58 to sever the tissue positioned in basket 28 from the targeted tissue mass. After knife 58 has been moved to the advanced position, a tissue sample 460 cut from targeted tissue mass 450 is positioned within basket 28. See FIG. 33.

In order to retrieve sample 460 from basket 28, firing module 300 is first disengaged from SULU 10 by cocking or compressing the movable handle of firing module 300 to allow C-tube 46 to be returned by spring 55 to a position in which notch 56 of flag 42 is positioned to engage trocar flange 34. Thereafter, trocar driver 100 is actuated to advance push/pull core 43 and flag 42 into engagement with trocar flange 34. Due to the configuration of flag 42 and trocar flange 34, notch 56 of flag 44 will be cammed into engagement with trocar flange 34 as push/pull core 43 is advanced. After flag 42 engages trocar flange 42, needle driver 100 is actuated to move push/pull core 43, trocar flange 34 and trocar 22 to a retracted position wherein basket 28 is positioned below window 64 formed in knife 58. Tissue sample 460 can now be removed from basket 28 through window 64. It is noted that in this position, knife 58 remains at a fixed position within target tissue mass 450. Thus, if additional tissue samples are desired, trocar driver 100 need only be actuated to move trocar 22 back to the advanced position. See FIG. 35. At this point, knife 58 can be retracted to expose basket 28 to target tissue mass 450. Thereafter, a

vacuum can be drawn through vacuum tube 95 to draw another tissue sample into basket 28 and knife 58 can be advanced to sever the tissue sample from tissue mass 450. If it is desired to obtain a tissue sample from a different portion of targeted tissue mass 450, the entire SULU 10 can be rotated to rotate basket 28 to any particular orientation with respect to tissue mass 450 to obtain a tissue sample from a particular location within tissue mass 450. For example, SULU 10 can be rotated 180° to obtain a second tissue sample from an opposite side of tissue mass 450. Alternately, SULU 10 can be rotated 30°, 60°, 90°, 120°, etc. Indicia 20 on tubular body 14 identifies the particular orientation of SULU 10. It is noted that SULU is preferably rotated when trocar 22 and knife 58 are in the advanced position as shown in FIG. 35.

When SULU 10 is hand-held during operation, firing module 300 is not required. Rather, with the aid of X-ray, the trocar tip is manually advanced through the targeted tissue mass such that basket 28 spans the entire width of target tissue mass 450. Thereafter, the procedure is identical to that disclosed above with respect to operation of the biopsy system when SULU 10 is mounted on table mount 420.

Referring to FIG. 36, trocar 22 can be retracted to a position proximal of window 64 to provide access to an internal channel 58' of tubular knife 58. Surgical instrumentation may be inserted through internal channel 58' prior to and/or after the biopsy procedure as needed. For example, the flexible delivery tube 502 of a site marker device 500 can be passed through knife 58 to position a hoop marker at the biopsy site. Such a site marker device is disclosed in PCT/US99/24867, filed October 22, 1999 and U.S. provisional application Serial No. 60/105,419, filed October 23, 1998, both of which are incorporated herein by reference in their entirety.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely

as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A biopsy system comprising:
 - a) a loading unit defining a longitudinal axis and including a trocar and a knife, the trocar defining a tissue receiving basket;
 - b) a trocar driver operably engaged with the trocar, the trocar driver being actuable to move the trocar axially between advanced and retracted positions; and
 - c) a knife driver operably connected to the knife, the knife driver being actuable to simultaneously rotate and axially move the knife between retracted and advanced positions; wherein the trocar driver and the trocar are operably connected through a connecting member, the connecting member being movable to disengage the trocar driver from the trocar.
2. A biopsy system according to Claim 1, wherein the trocar and the knife are tubular, and the trocar is slidably positioned within the knife.
3. A biopsy system according to Claim 1, further including a trocar flange connected to a proximal end of the trocar, the trocar flange being operably engaged with the trocar driver.
4. A biopsy system according to Claim 3, further including a drive shaft extending between the trocar driver and the loading unit, the connecting member being secured to one end of the drive shaft and being movable from a first position engaged with the trocar flange to a second position disengaged from the trocar flange.

5. A biopsy system according to Claim 1, wherein the connecting member includes a flag member which is secured to the drive shaft, the flag member having a notch configured to engage the trocar flange.

6. A method for biopsying tissue comprising the following steps:

a) providing a biopsy system including a loading unit having a trocar defining a tissue receiving basket and a knife, a trocar driver operably engaged with the trocar to move the trocar between advanced and retracted positions, a knife driver for moving the knife between retracted and advanced positions and a firing mechanism for advancing the trocar into a targeted tissue mass;

b) positioning the loading unit with the trocar aligned with the targeted tissue mass;

c) disengaging the trocar driver from operable engagement with the trocar; and

d) activating the firing mechanism to advance the trocar into the targeted tissue mass.

7. A method according to Claim 6, further including the following step:

e) drawing a vacuum within the trocar to draw tissue into the tissue receiving basket.

8. A method according to Claim 7, further including the following step:

f) actuating the knife driver to advance the knife from the retracted to the advanced position to sever tissue positioned in the tissue receiving basket from the targeted tissue mass.

9. A method according to Claim 8, further including the following step:
- g) moving the trocar driver into operable engagement with the trocar, and thereafter, moving the trocar to the retracted position, wherein the tissue receiving basket is accessible.
10. A method according to Claim 9, further including the following step:
- h) actuating the trocar driver to advance the trocar to the advanced position to retrieve another tissue sample.

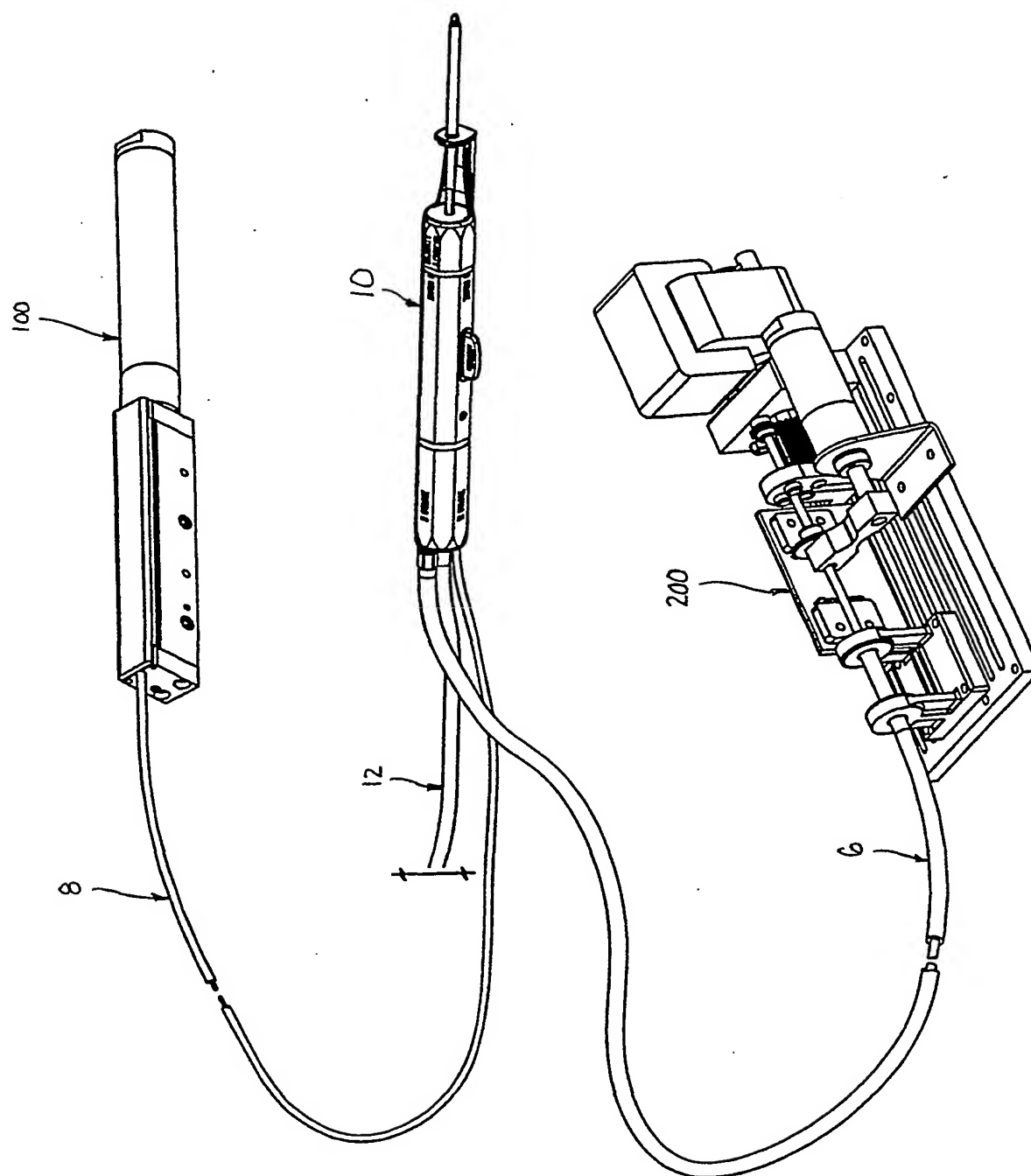


FIG. 1

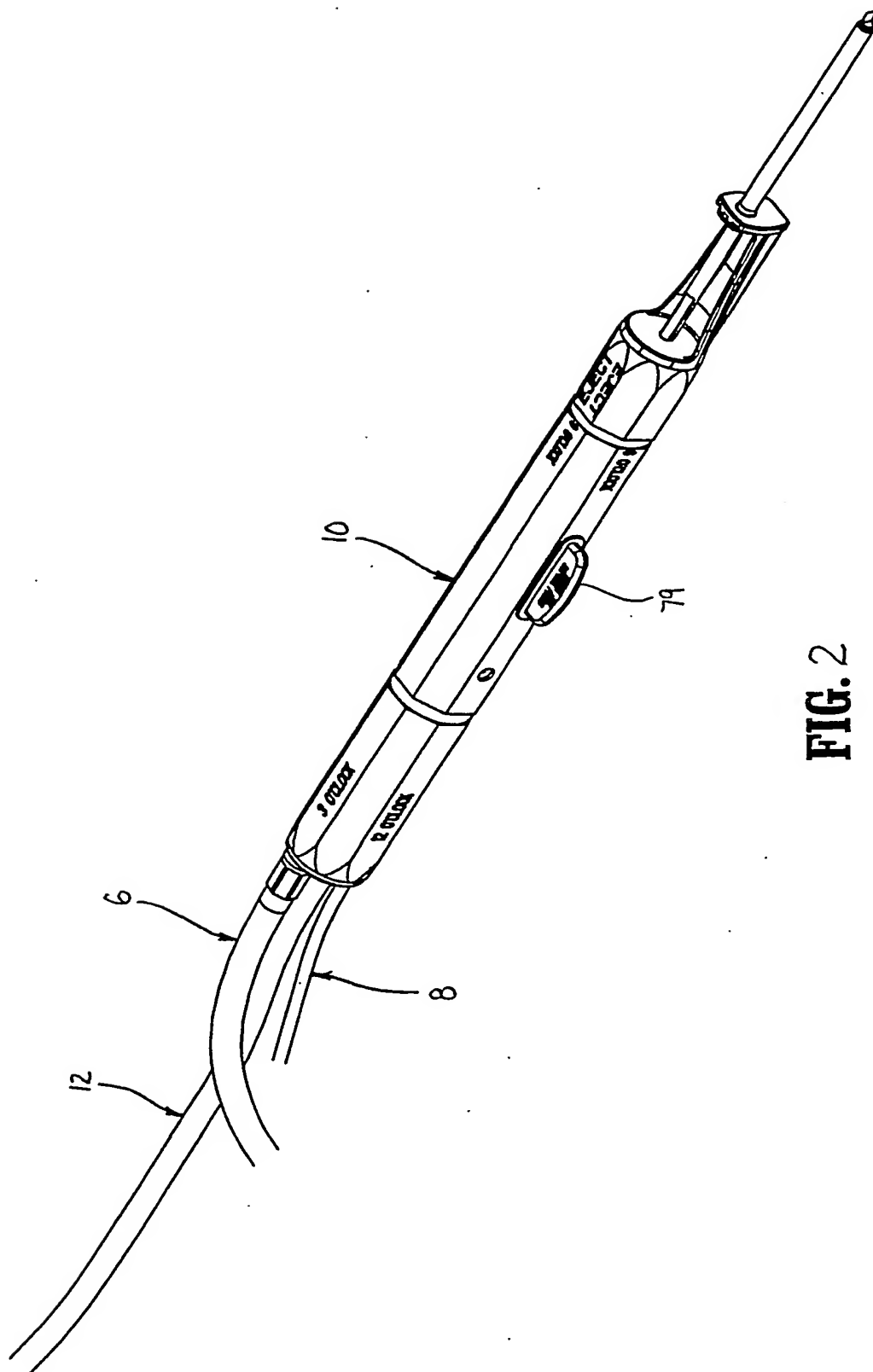
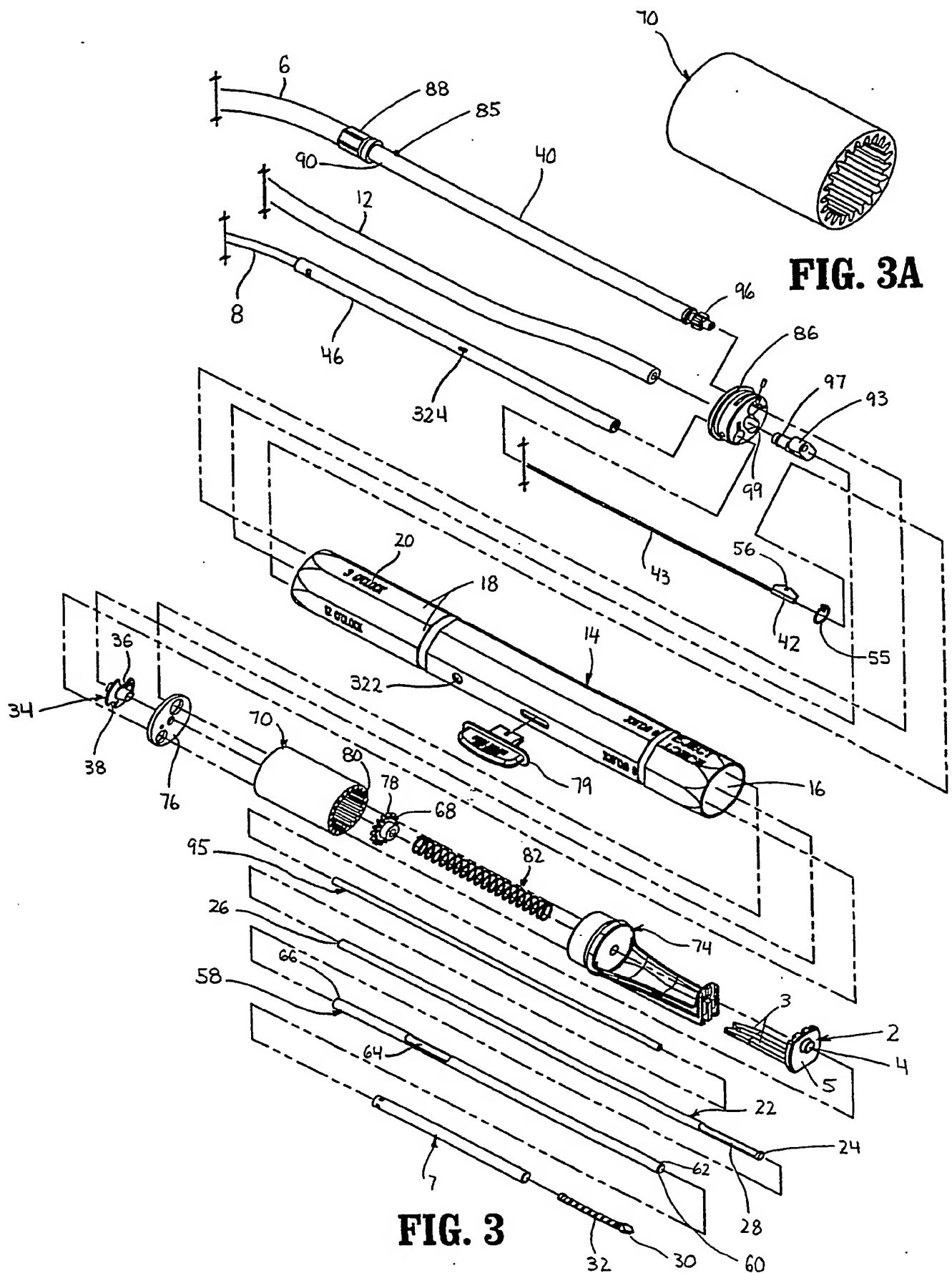


FIG. 2



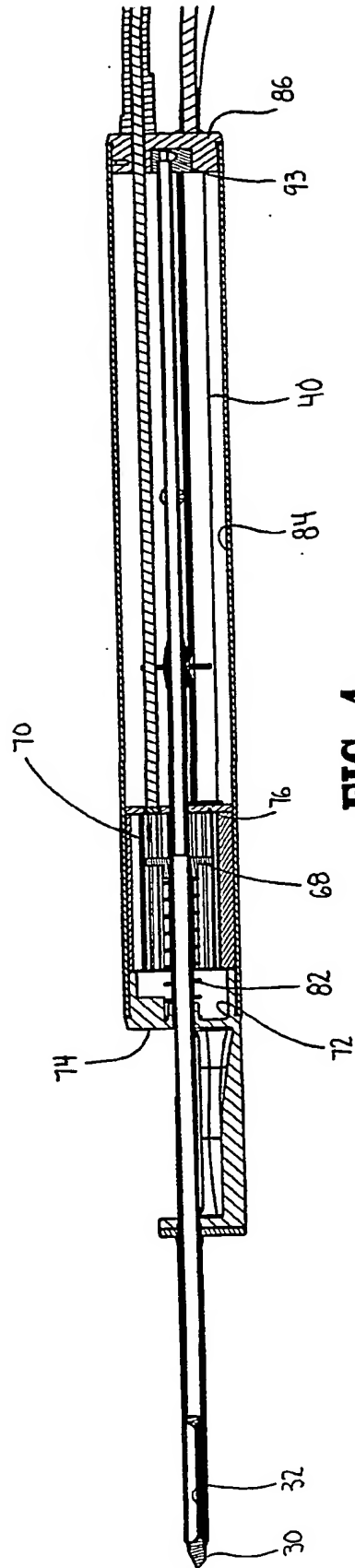


FIG. 4

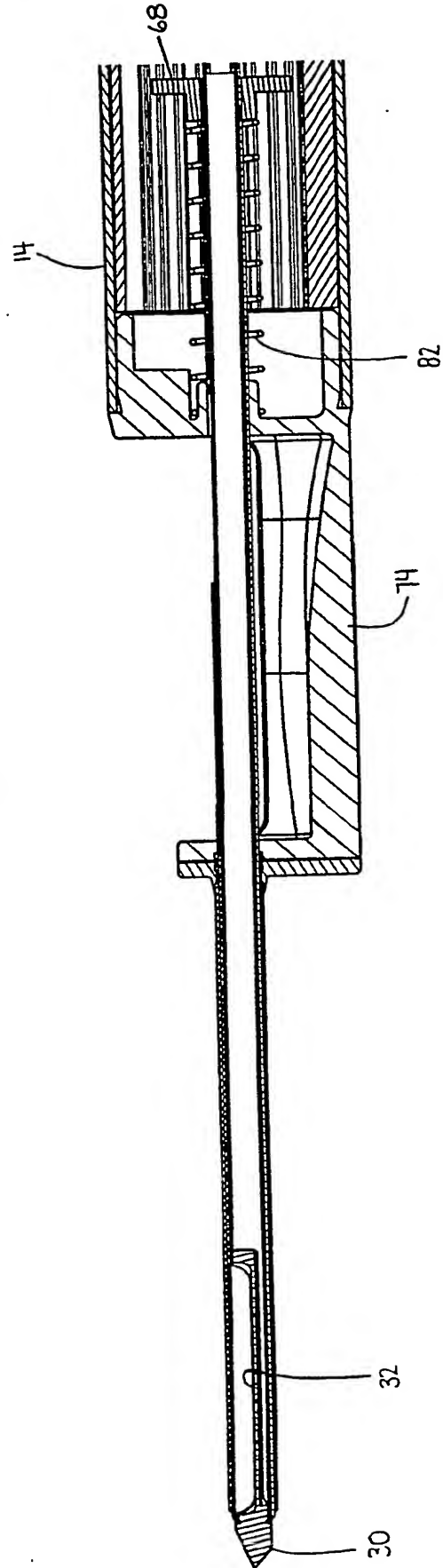


FIG. 5

5/27

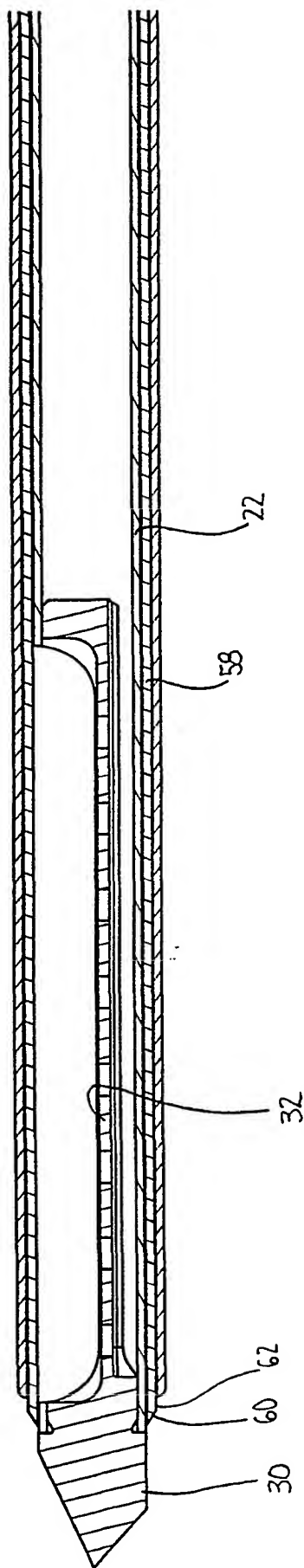
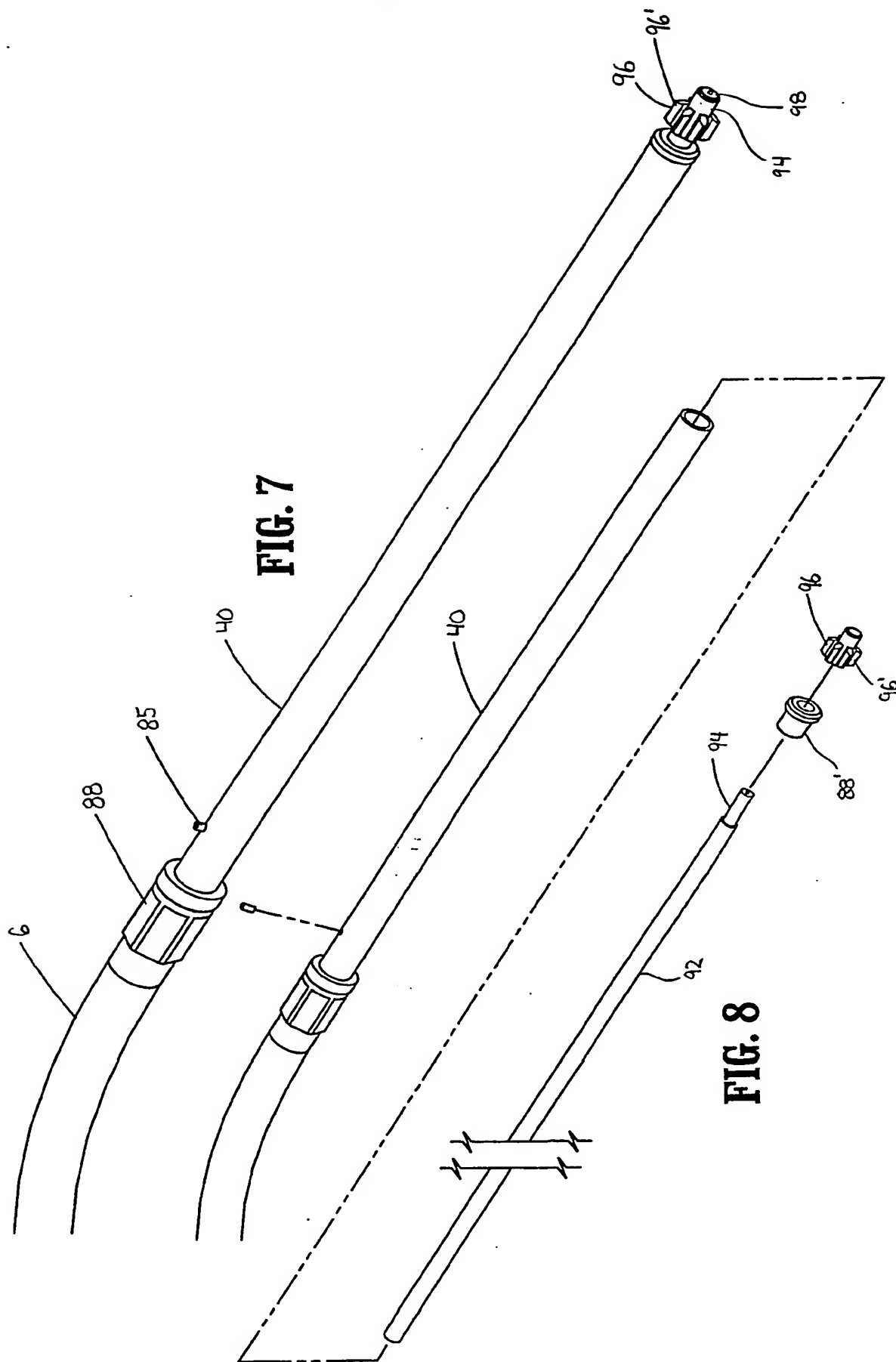
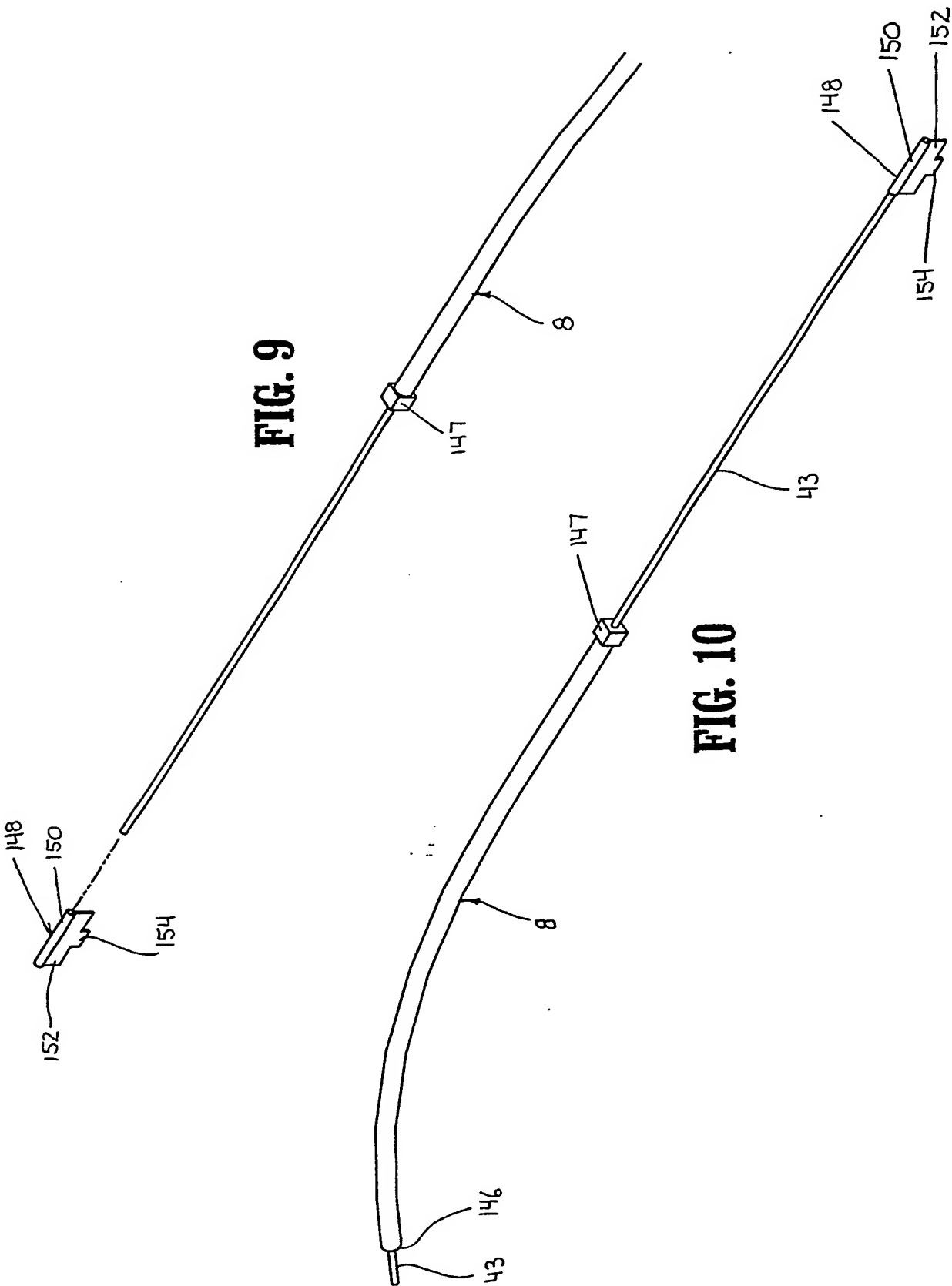


FIG. 6





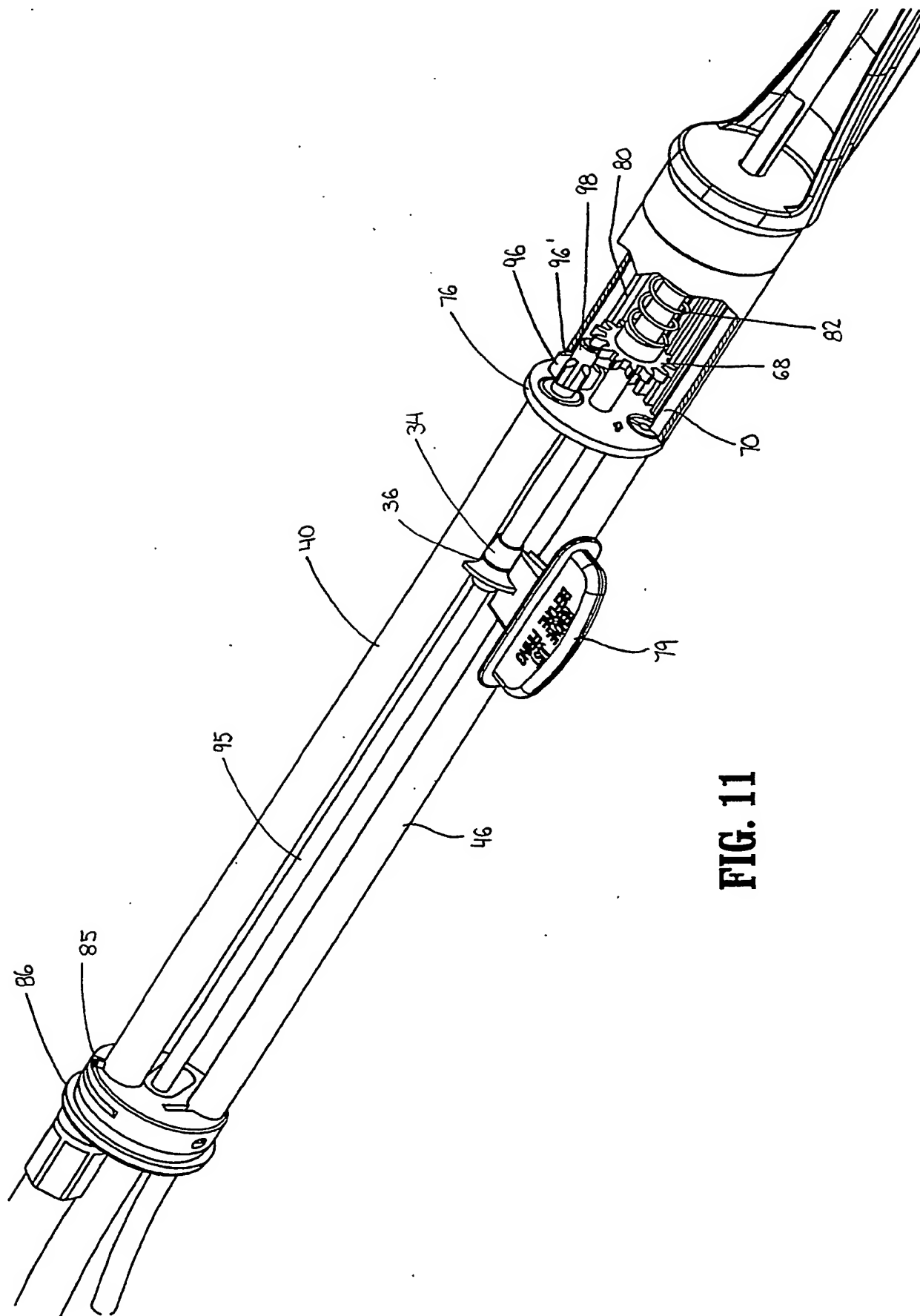
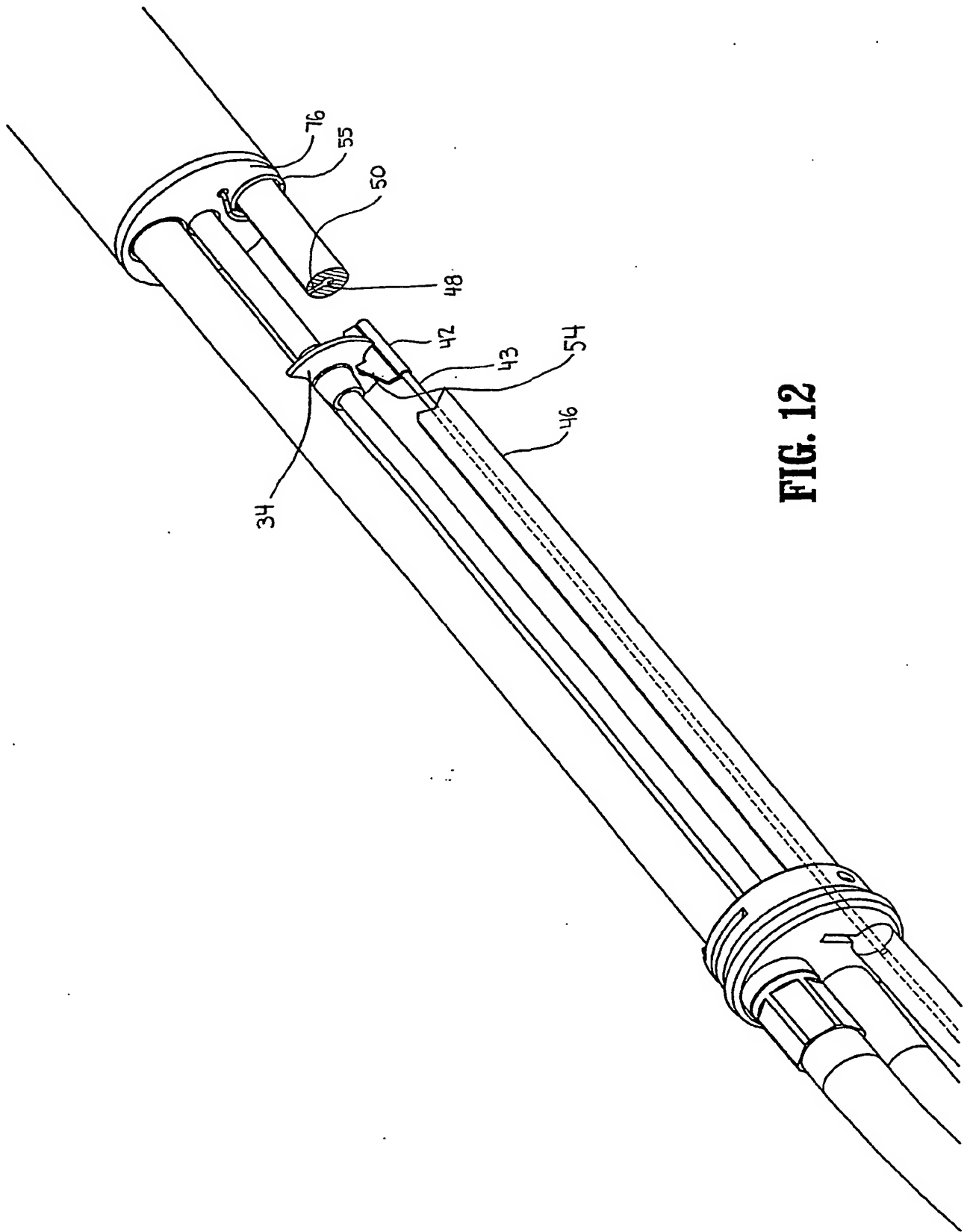
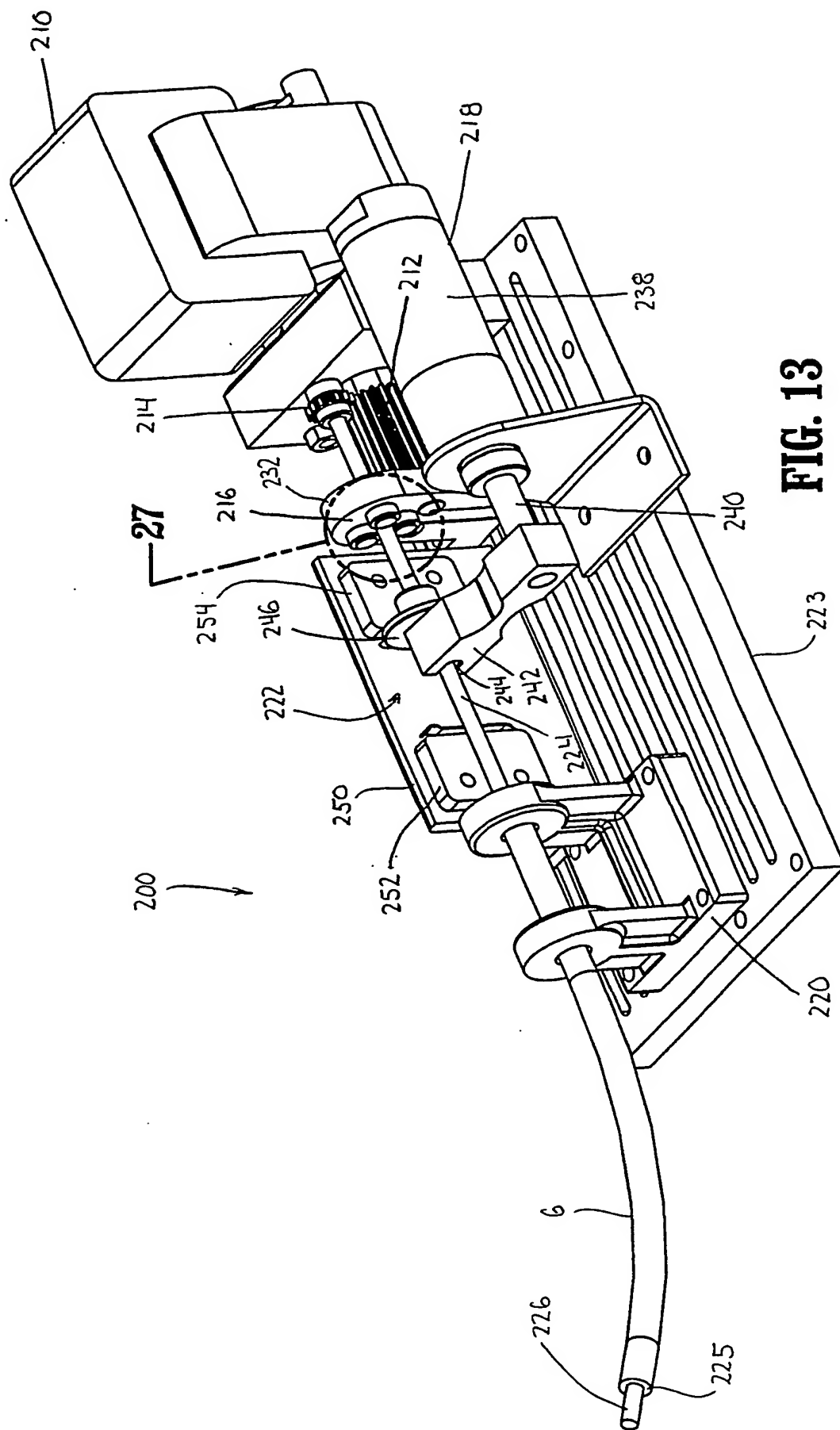
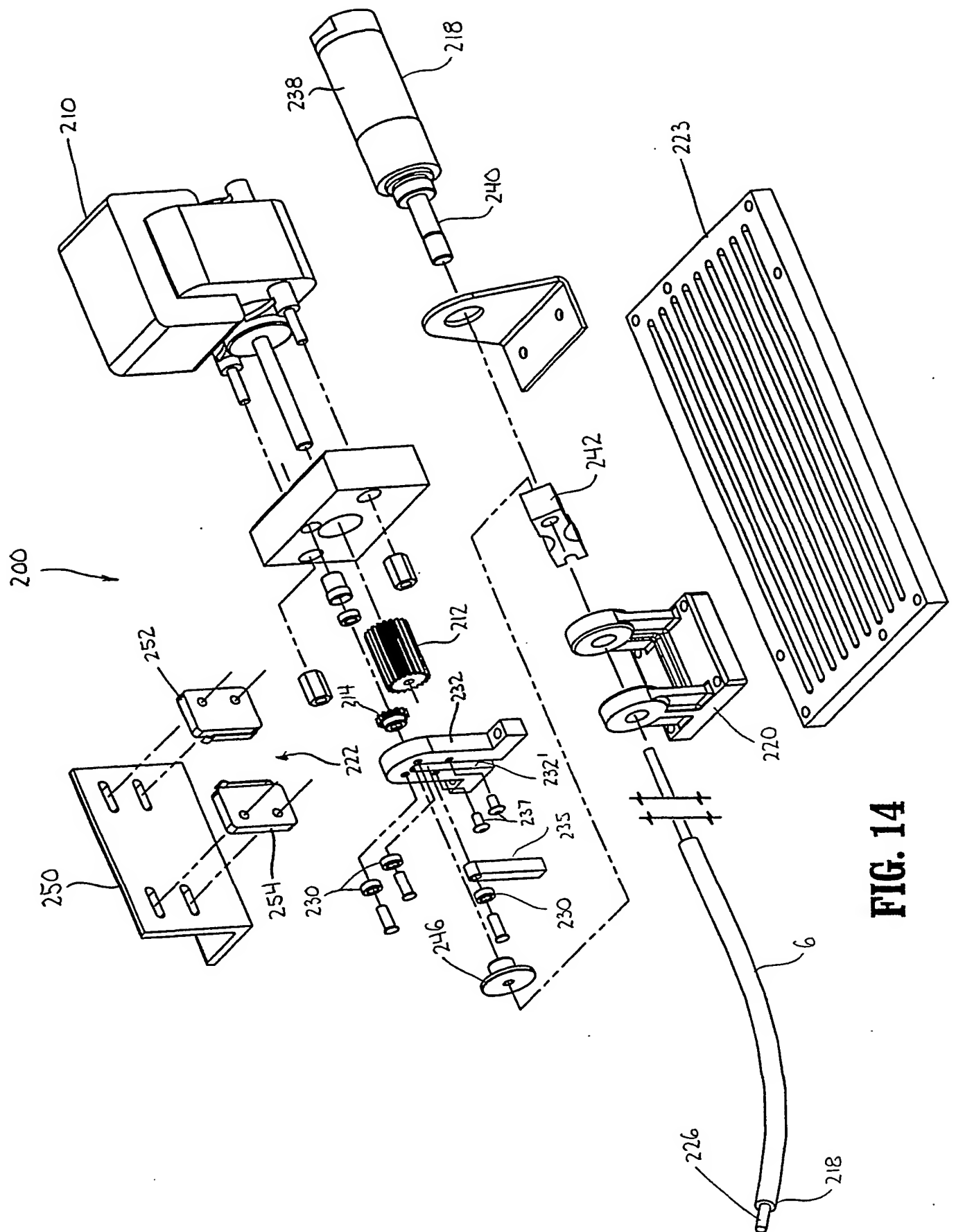


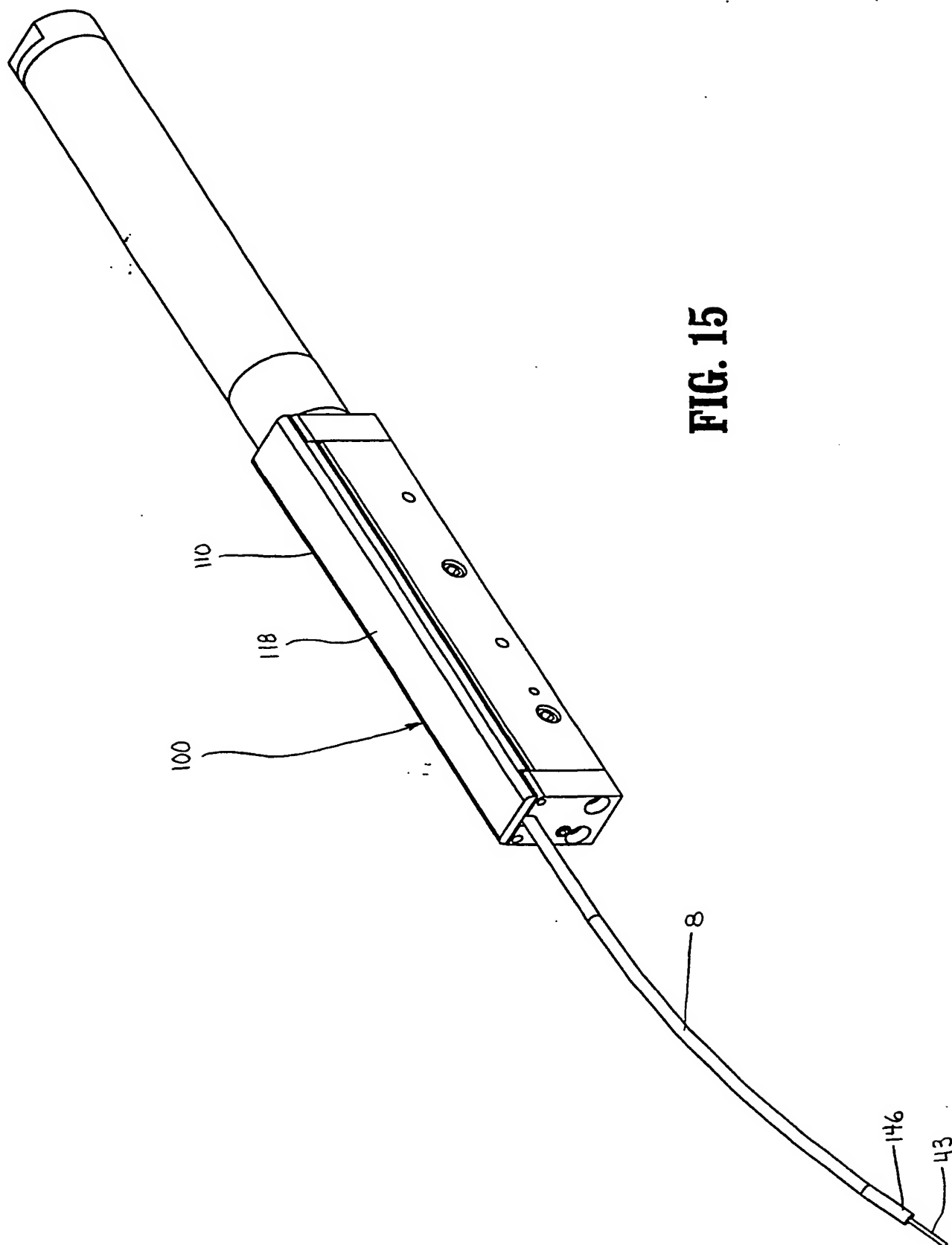
FIG. 11





11/27

**FIG. 14**



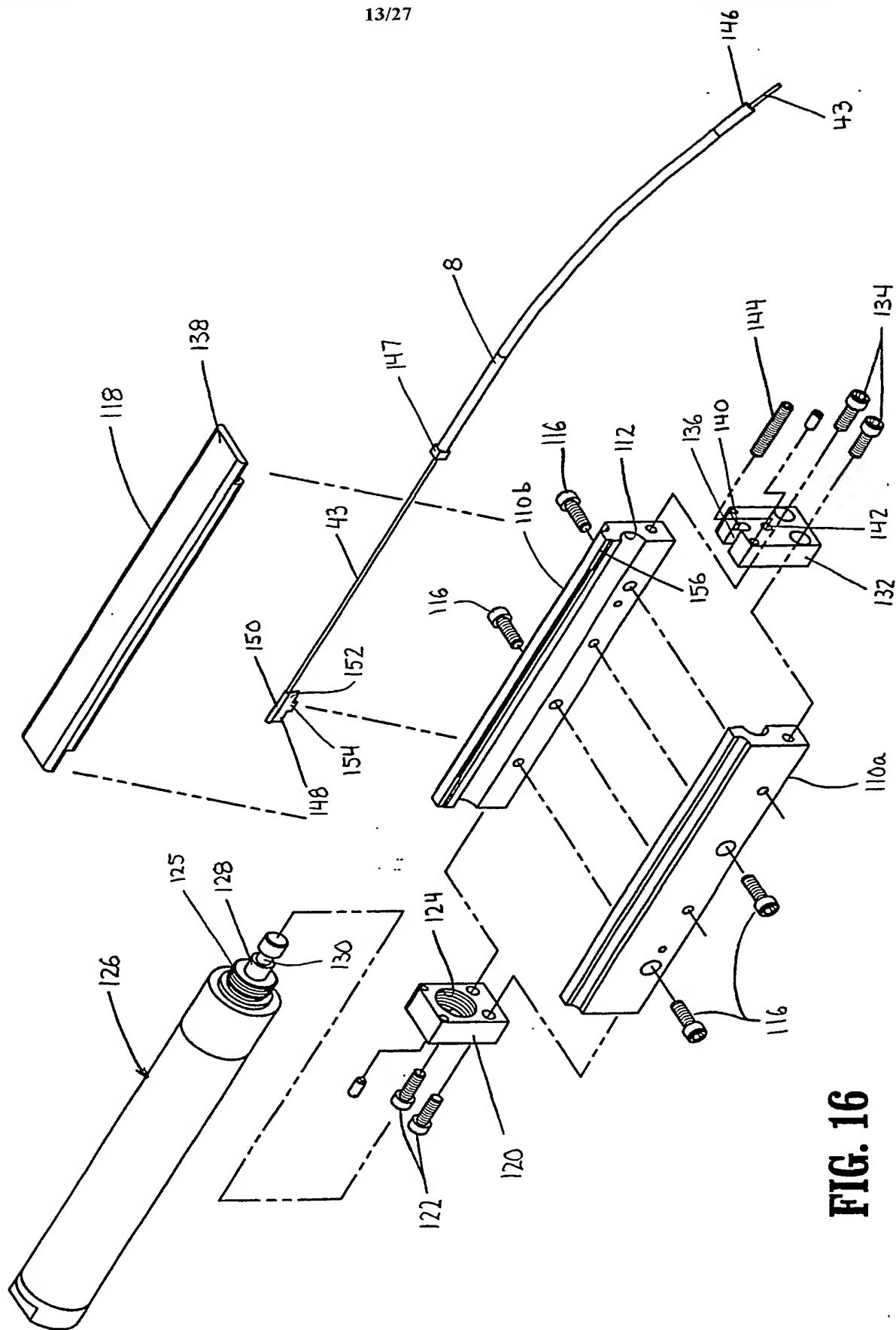


FIG. 16

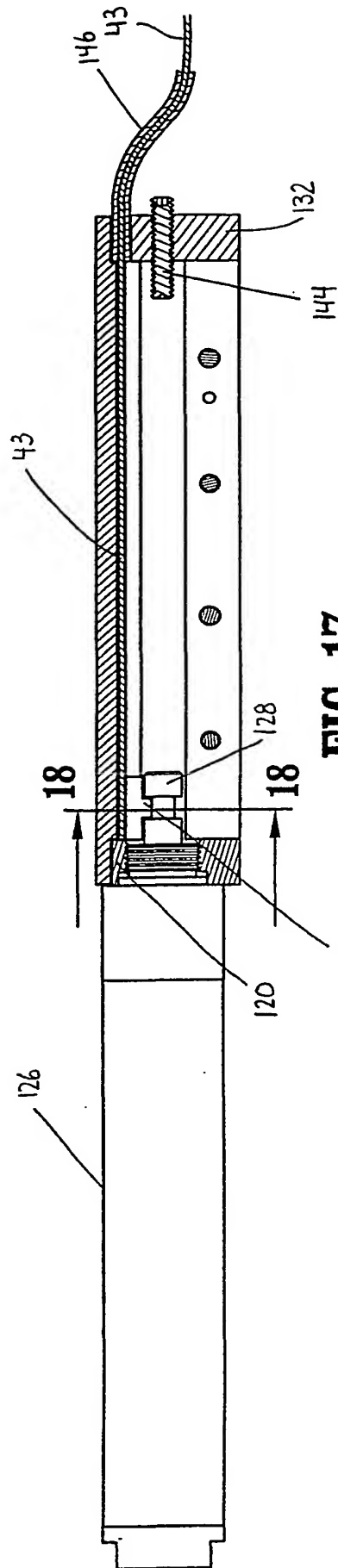


FIG. 17

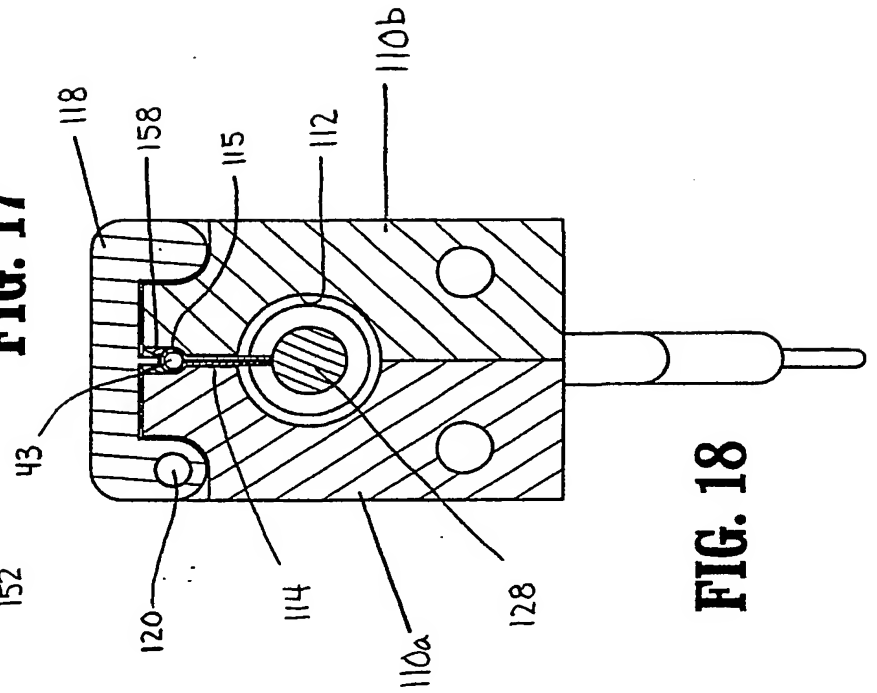
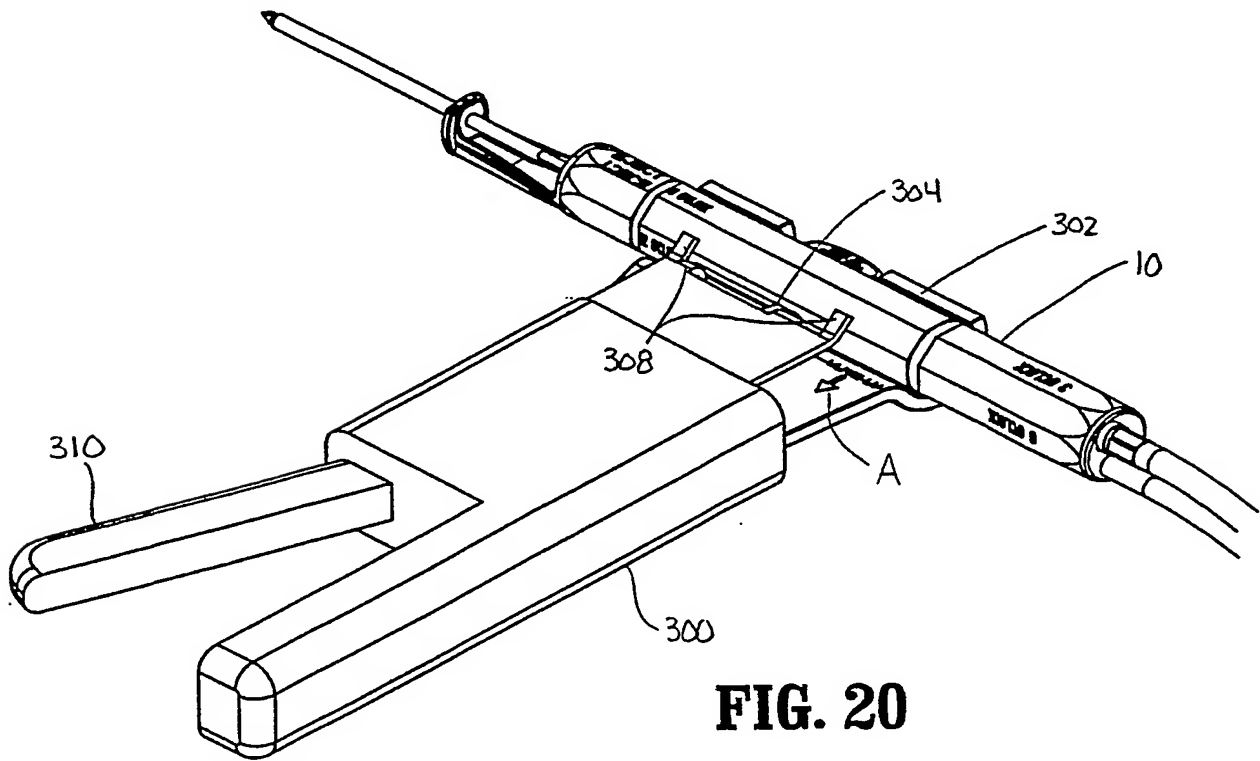
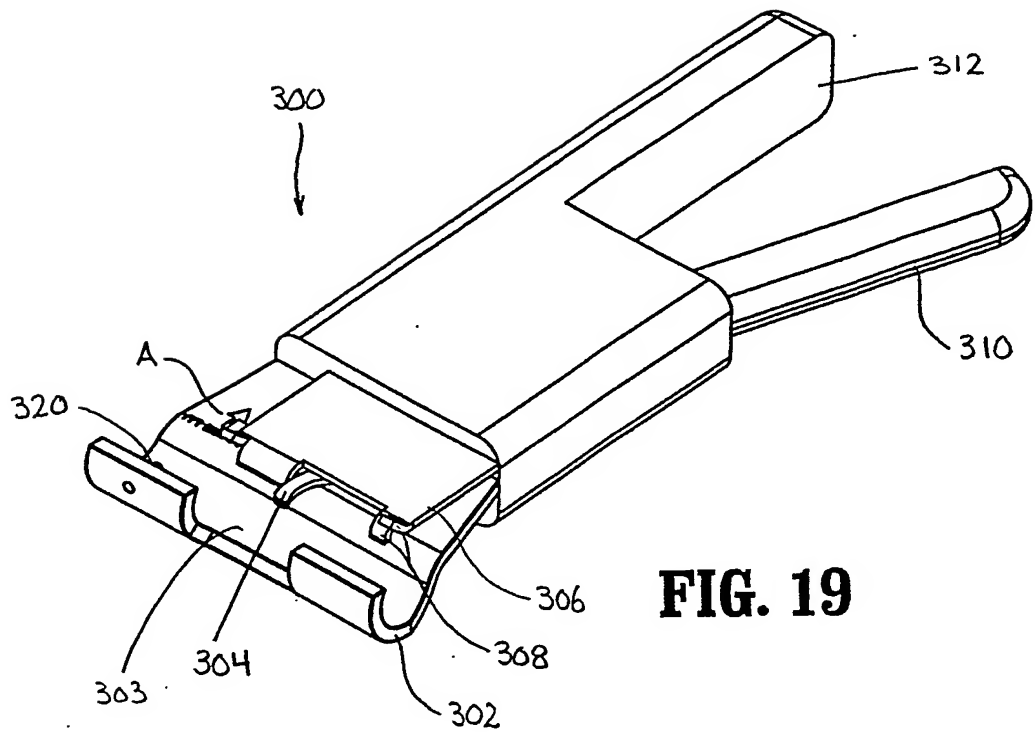
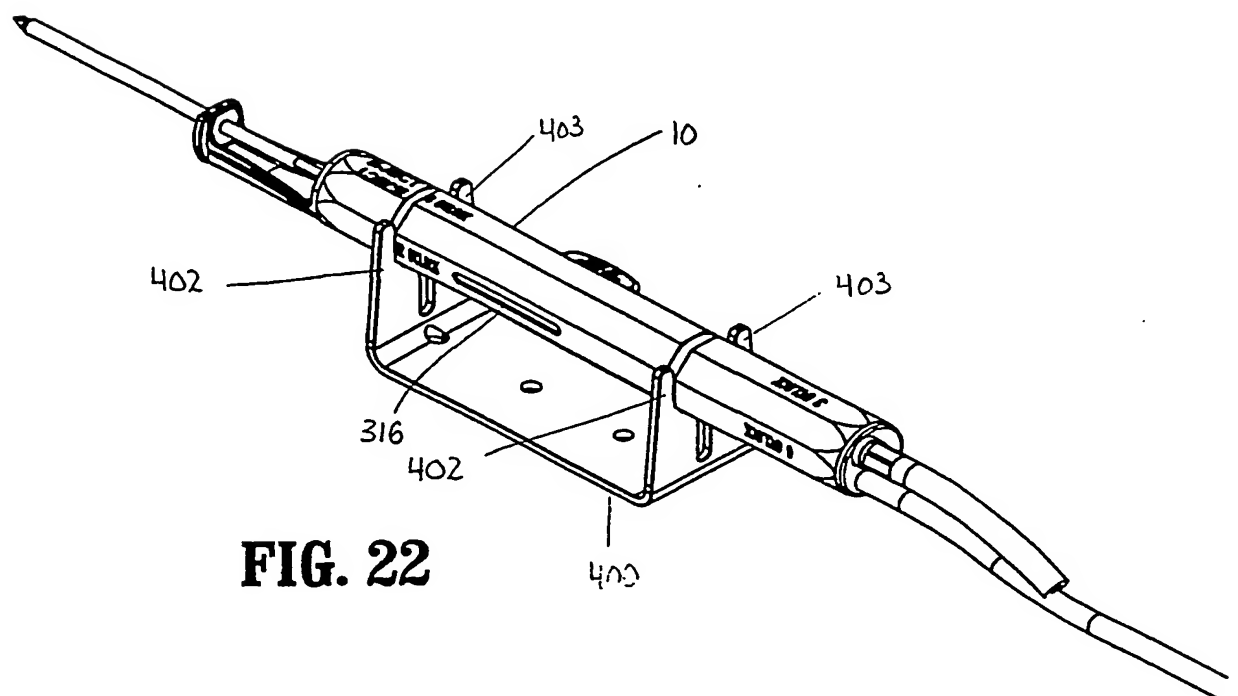
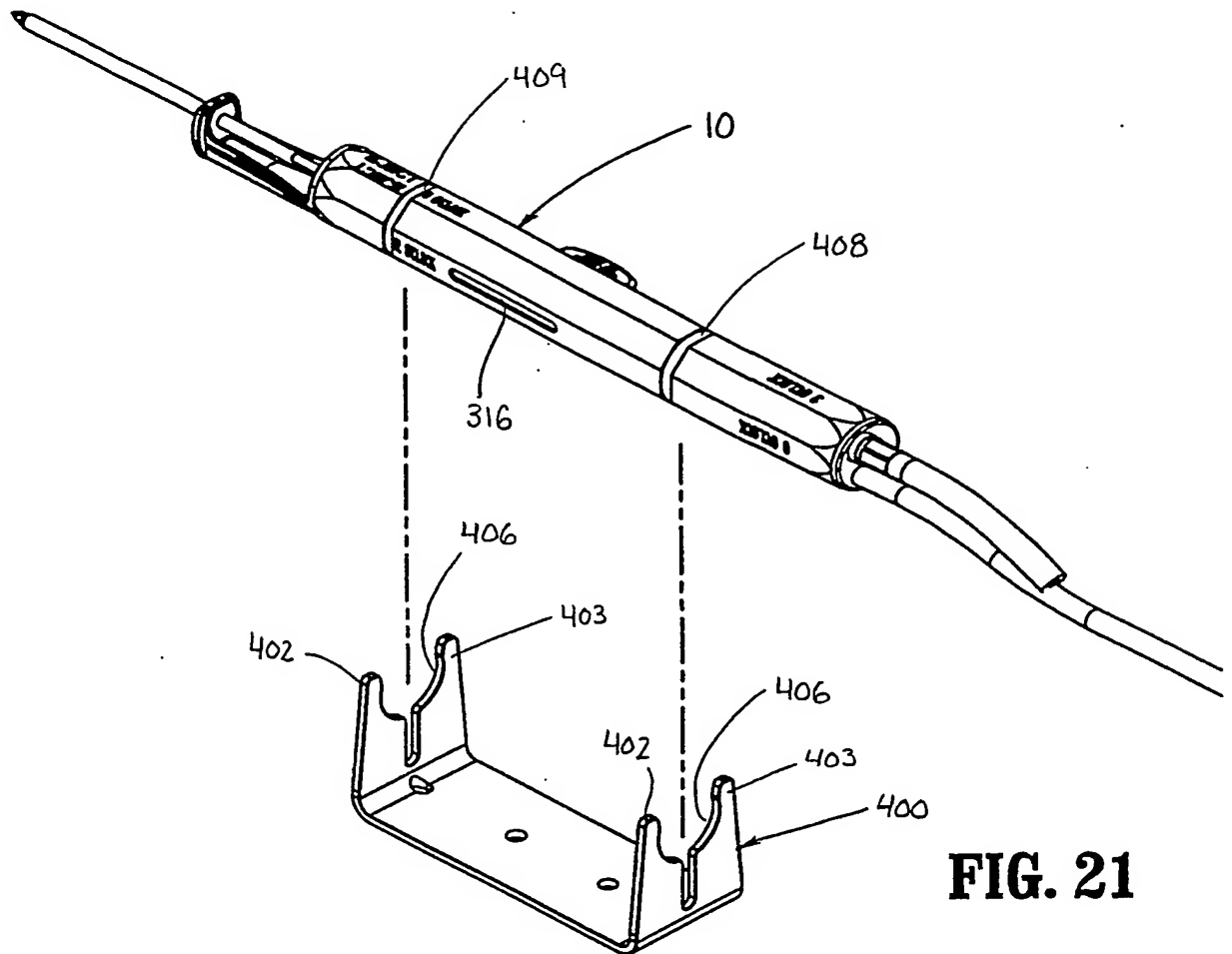
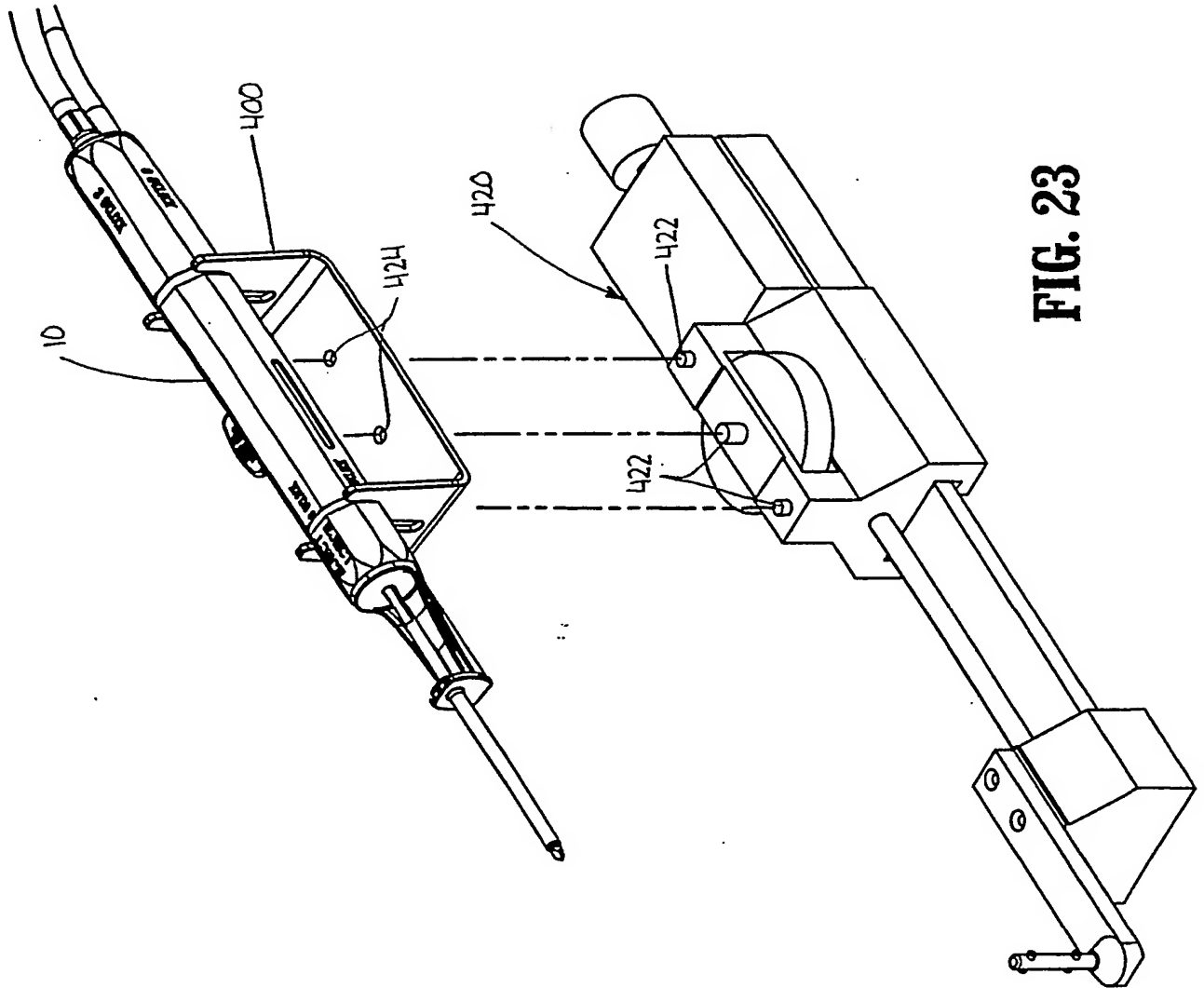
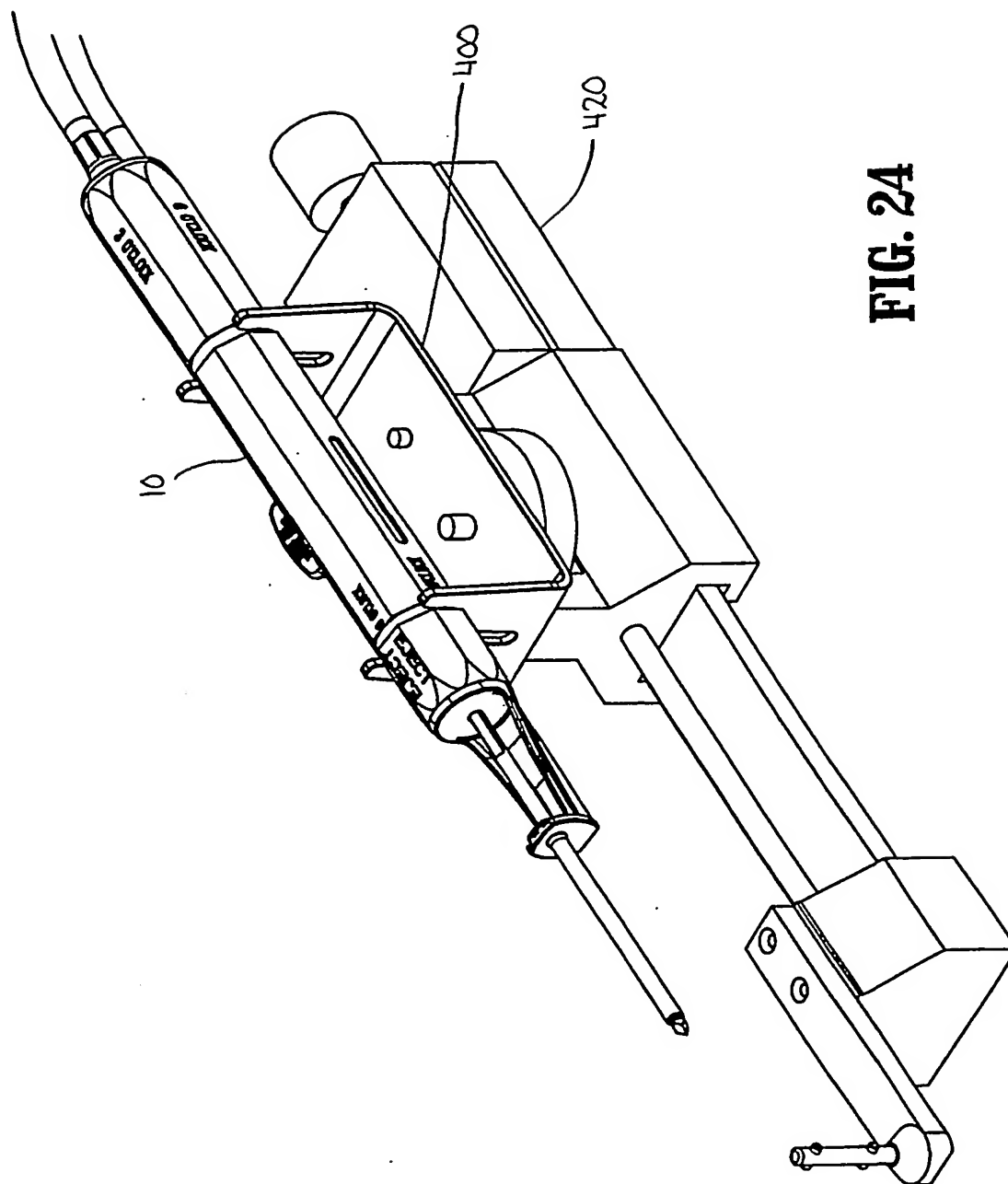


FIG. 18









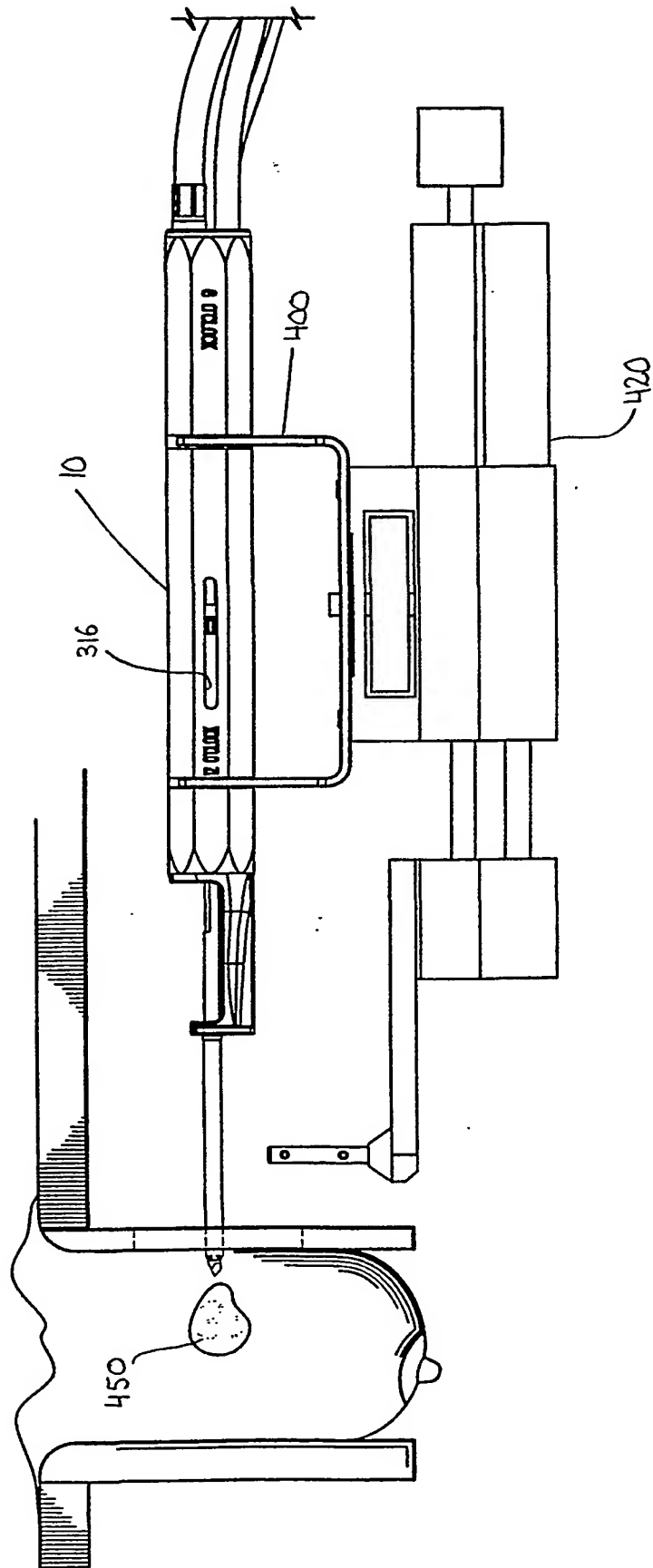


FIG. 25

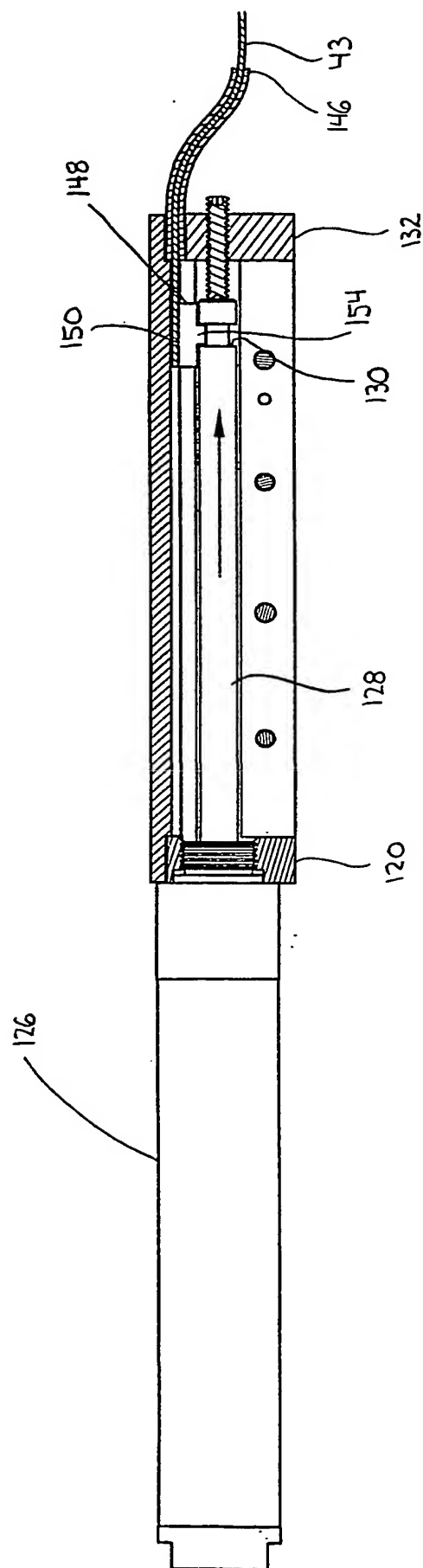
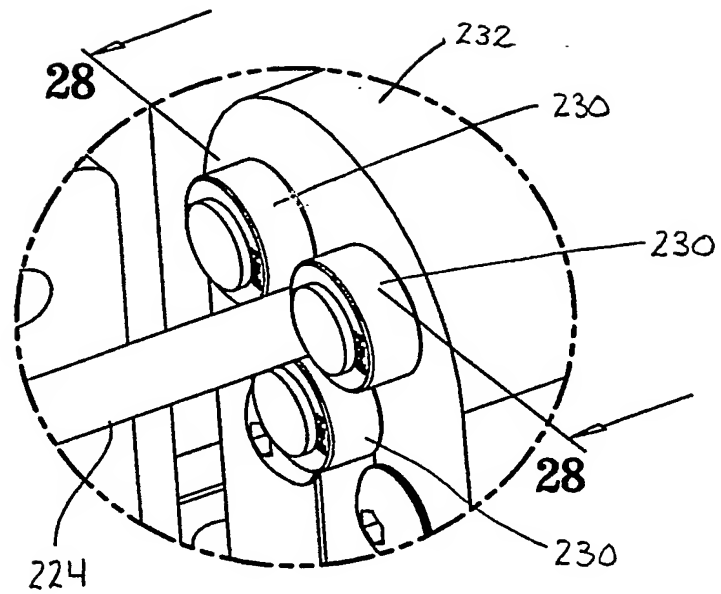
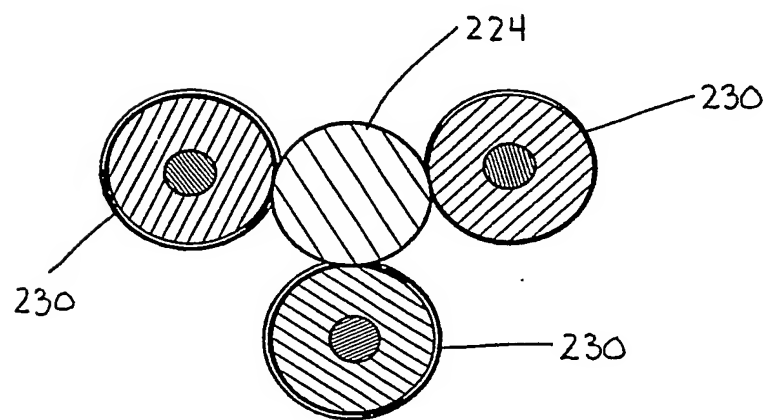


FIG. 26

**FIG. 27****FIG. 28**

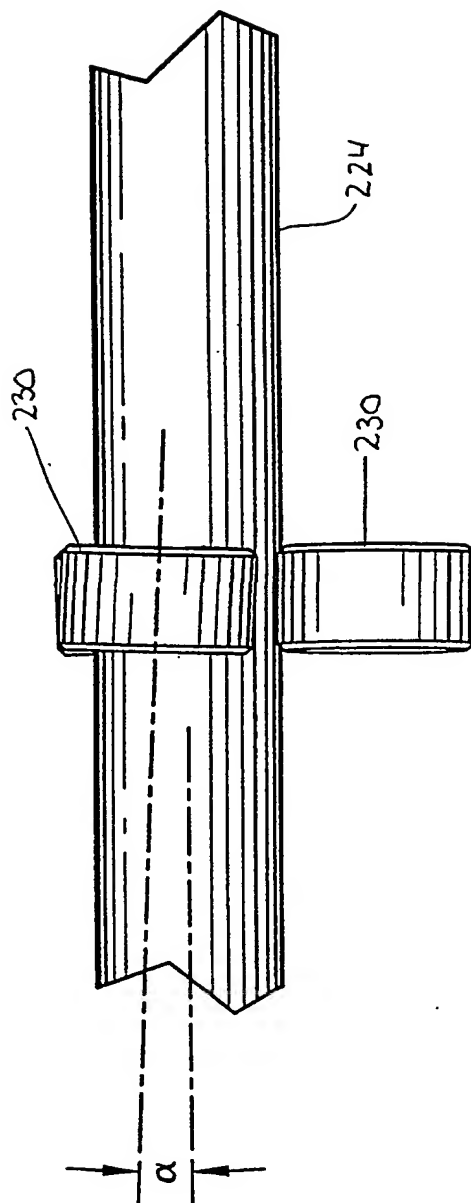
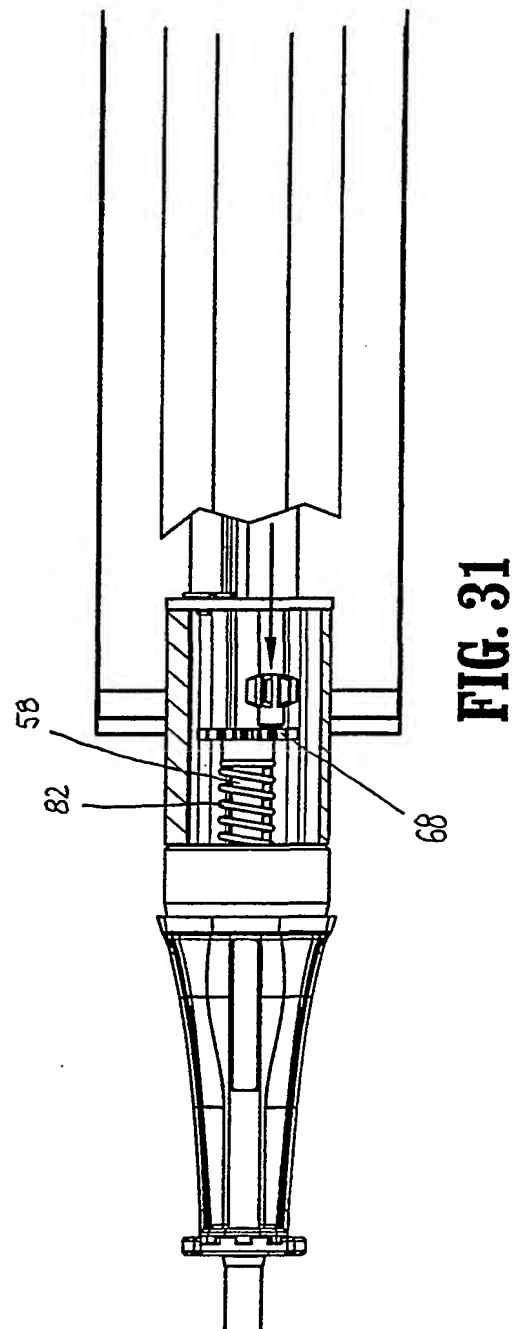
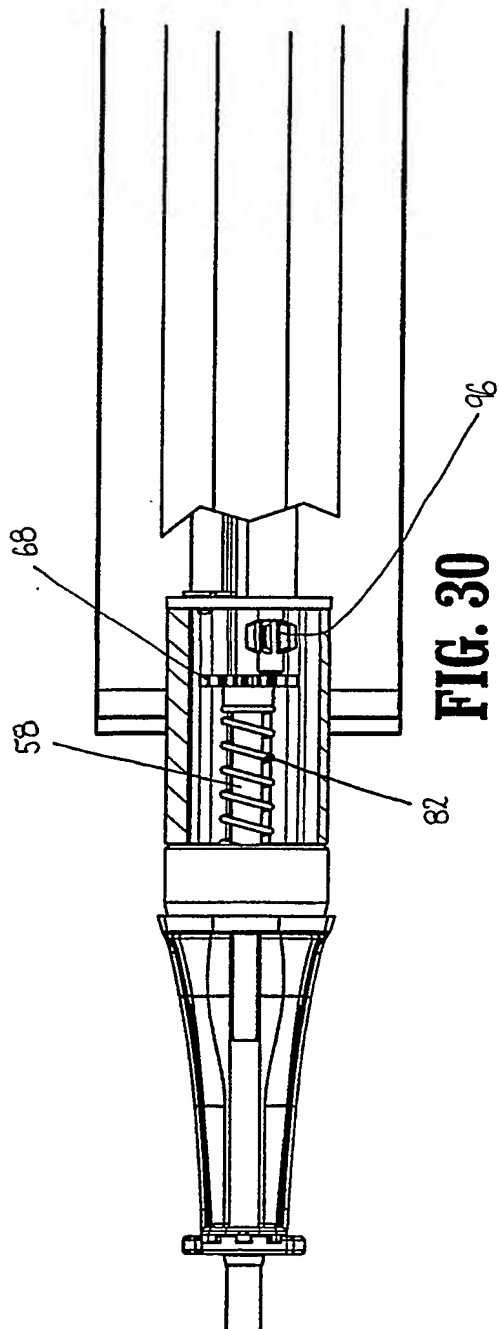
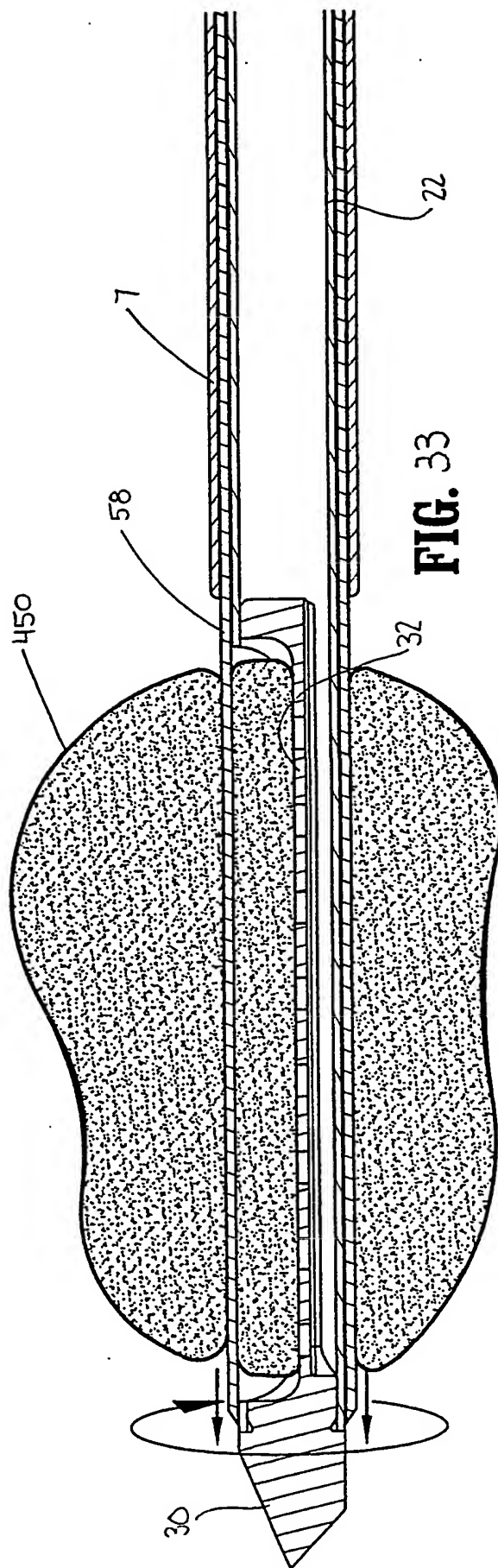
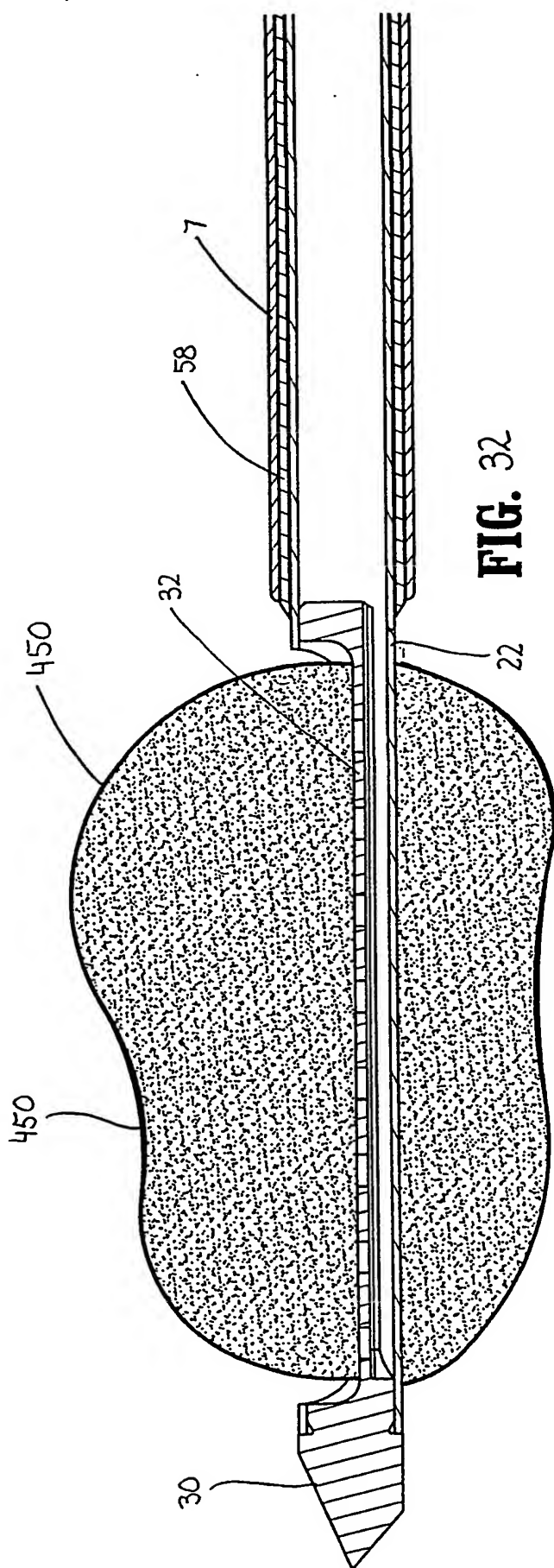


FIG. 29





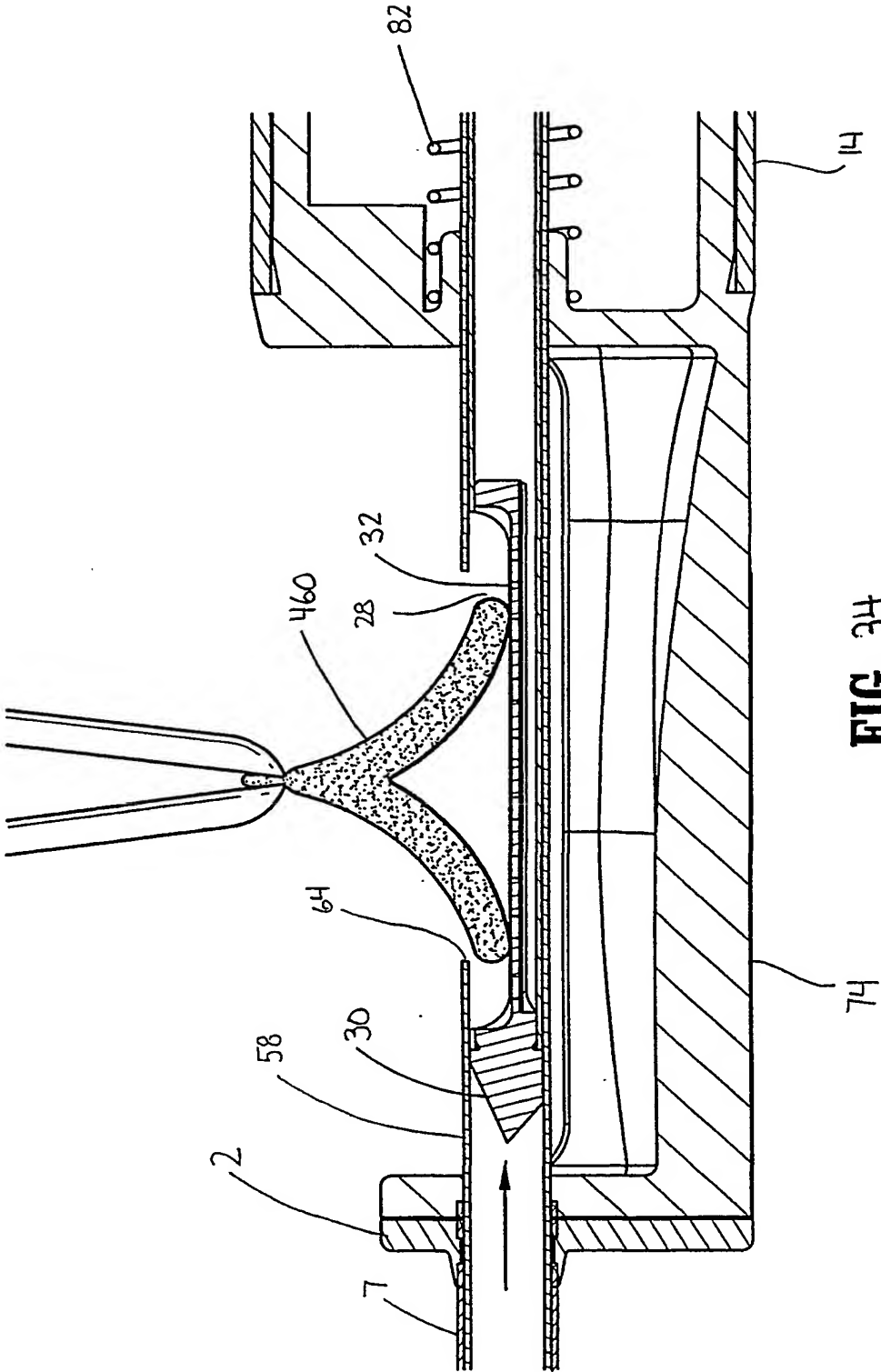


FIG. 34

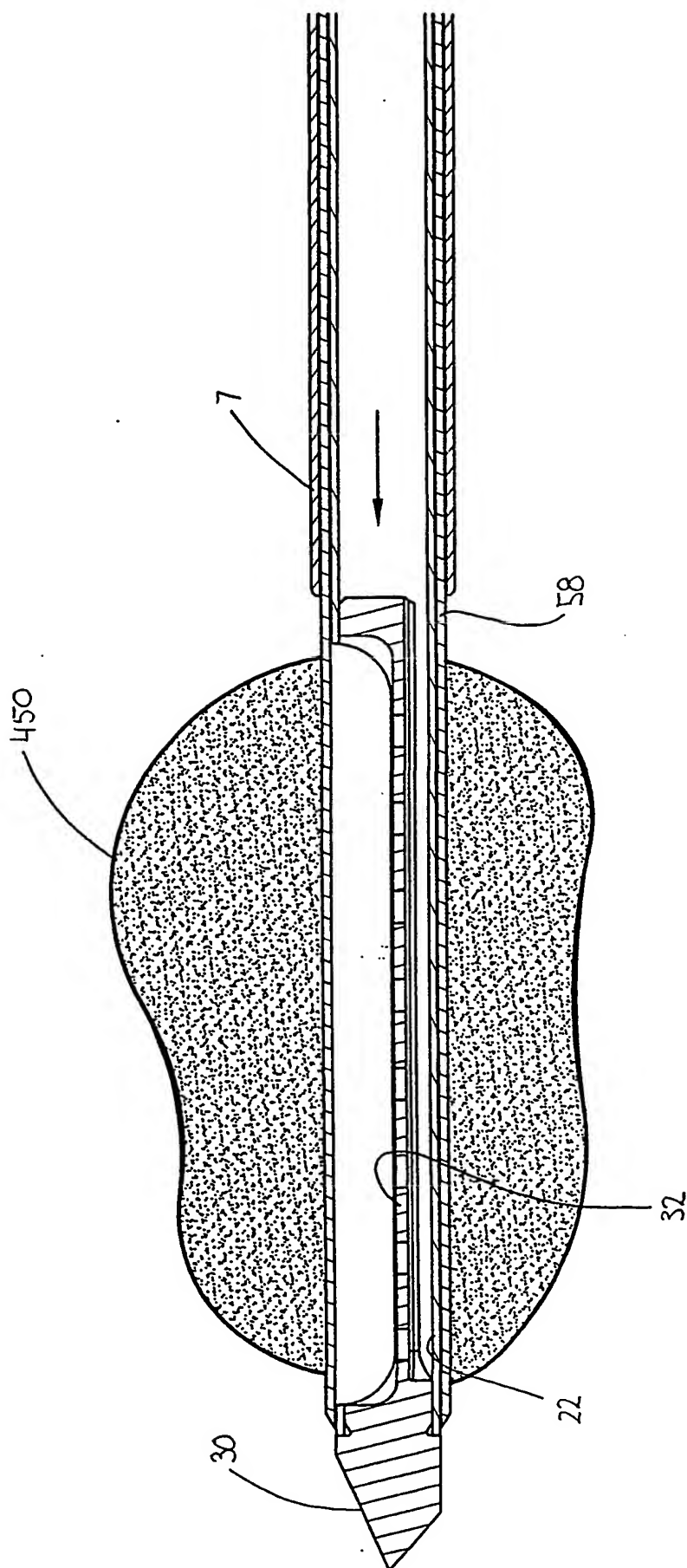


FIG. 35

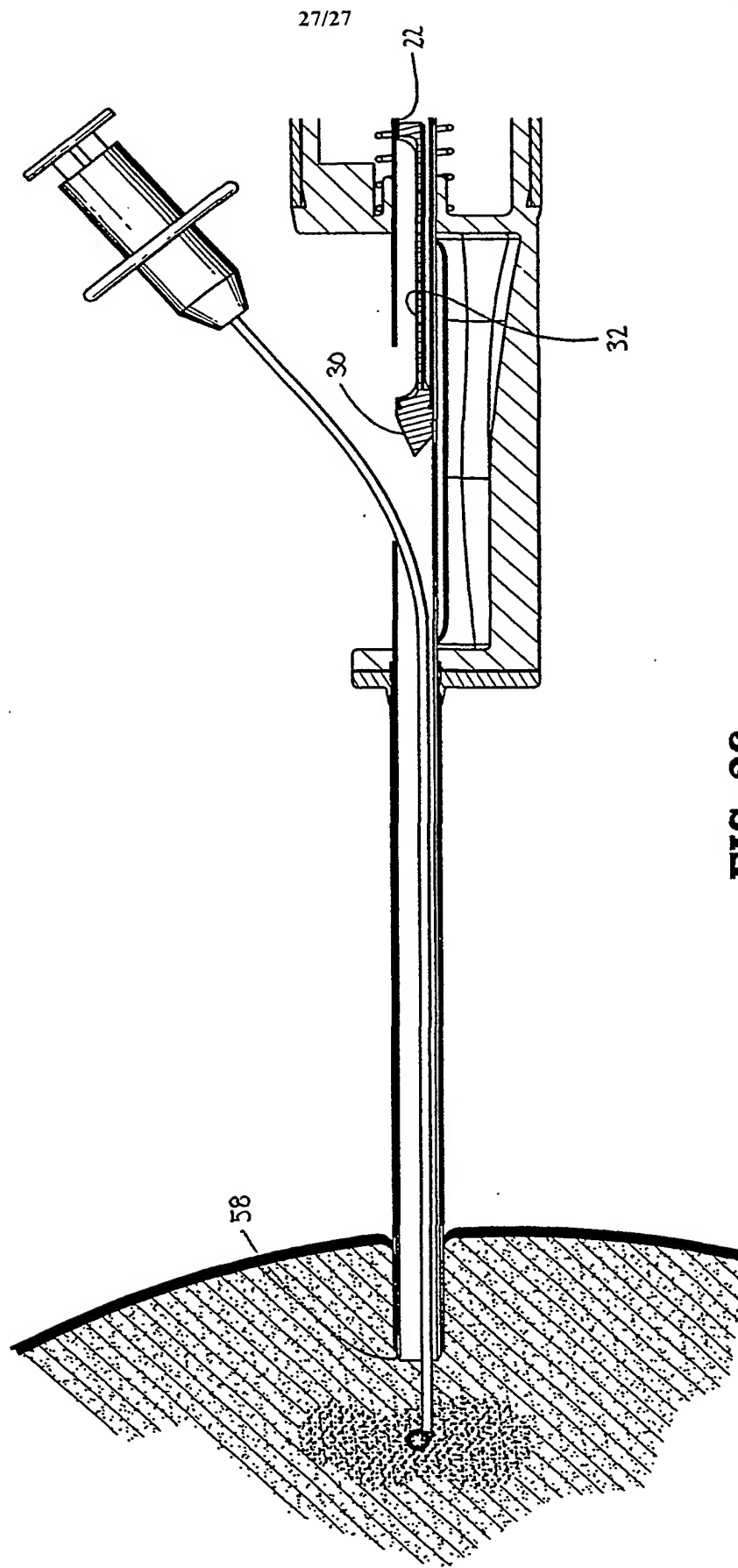


FIG. 36

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/26575

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 25465 A (BIOPSY MEDICAL INC) 28 September 1995 (1995-09-28)	1
Y	page 33, line 5 - line 24; figures 6A-H, 18	2
Y	WO 99 15079 A (UNITED STATES SURGICAL CORP) 1 April 1999 (1999-04-01) page 21, line 3 - line 15; figures 21, 22	2
A	US 6 027 458 A (JANSSENS JACQUES PHILLIBERT) 22 February 2000 (2000-02-22) column 5, line 36 - line 40; figures 14, 15	1, 2
A	EP 0 995 400 A (ETHICON ENDO SURGERY) 26 April 2000 (2000-04-26) column 13, line 44 - column 14, line 6; figures 2, 5	1

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

16 January 2002

Date of mailing of the international search report

22/01/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Mayer, E

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/26575

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 27441 A (SANTIS STEPHEN A. DE) 19 October 1995 (1995-10-19) column 33, line 30 -column 34, line 3; figure 35 -----	3-5
A	WO 00 30546 A (UNITED STATES SURGICAL CORP ;LEHN RANDOLPH (US); RETHY CSABA L (US) 2 June 2000 (2000-06-02) abstract -----	1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/26575

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9525465	A	28-09-1995	US 5526822 A	18-06-1996
			CA 2186283 A1	28-09-1995
			EP 0751744 A1	08-01-1997
			JP 9510638 T	28-10-1997
			US 5928164 A	27-07-1999
			US 5980469 A	09-11-1999
			WO 9525465 A2	28-09-1995
			US 5649547 A	22-07-1997
			US 5775333 A	07-07-1998
			US 2001007925 A1	12-07-2001
WO 9915079	A	01-04-1999	US 6142955 A	07-11-2000
			AU 728656 B2	18-01-2001
			AU 9491298 A	12-04-1999
			EP 1026992 A1	16-08-2000
			JP 2001517470 T	09-10-2001
			WO 9915079 A1	01-04-1999
US 6027458	A	22-02-2000	AU 1361997 A	28-07-1997
			EP 0959774 A1	01-12-1999
			JP 2000502576 T	07-03-2000
EP 0995400	A	26-04-2000	AU 5602799 A	04-05-2000
			EP 0995400 A1	26-04-2000
			JP 2000152941 A	06-06-2000
			US 6273862 B1	14-08-2001
WO 9527441	A	19-10-1995	US 5511556 A	30-04-1996
			AU 2278395 A	30-10-1995
			US 5971939 A	26-10-1999
			WO 9527441 A1	19-10-1995
			US 5469860 A	28-11-1995
			US 5560373 A	01-10-1996
			US 5817033 A	06-10-1998
WO 0030546	A	02-06-2000	AU 1829900 A	13-06-2000
			EP 1133260 A1	19-09-2001
			WO 0030546 A1	02-06-2000

THIS PAGE BLANK (USPTO)